



**DEPARTMENT**

**of**

**DIS TRUST**




# OPERATION WARP SPEED [OWS]

## Operation Warp Speed



Official seal of Operation Warp Speed

<b>Active</b>	May 15, 2020 – February 24, 2021 (285 days)
<b>Disbanded</b>	Transitioned to <a href="#">White House COVID-19 Response Team</a>
<b>Country</b>	<a href="#">United States</a>
<b>Allegiance</b>	 <a href="#">United States</a>
<b>Part of</b>	<a href="#">U.S. Department of Defense</a> <a href="#">U.S. Department of Health and Human Services</a> <a href="#">Other various government agencies</a>

According to the search results, the 8 companies that received funding of around \$11 billion from Operation Warp Speed as of August 2020 to expedite development and preparation for manufacturing their COVID-19 vaccine candidates were:

1. Johnson & Johnson (Janssen Pharmaceutical) - \$1 billion
2. AstraZeneca–University of Oxford and Vaccitech - \$1.2 billion
3. Moderna - \$1.5 billion
4. Novavax - \$1.6 billion
5. Pfizer & BioNTech - \$1.95 billion
6. Sanofi & GlaxoSmithKline - \$2.1 billion
7. Regeneron - \$450 million
8. Emergent BioSolutions - \$628 million

The search results provide a comprehensive list of the 8 companies that received significant funding from Operation Warp Speed to accelerate the development and manufacturing of their COVID-19 vaccine candidates as of August 2020. [1](#) [3](#) [4](#)

DoD + HHS

In total 8 companies were backed by  
OWS



# OWS MCM Enterprise & Responsible Participants

OWS Injectables, therapies & other biological MCMs			
Drug Name(s):	Manufacturers:	Market Status:	Involved Government Affiliations & Agencies:
Remdesivir/Veklury	Gilead+ Ligand Pharmaceuticals	1st Use May 2020, Full Approval Oct 2020 All ages by April 2022	USAMRIID, NIH, UNC Chapel Hill, Univ AL, Vanderbilt, Columbia, DTRA, JSTO-CBD, DARPA
Lagevrio/ Molnupiravir	Merck +Ridgeback Bio	First Authorization Dec 2021	Emory DRIVE LLC
Paxlovid/ nirmatrelvir+ritonavir	Pfizer	Full Approval May 2023 First Use Dec 2021	
Bamlanivimab/LY-CoV555	Abcellera +Eli Lilly	EUA Nov 2020,Renewed March 2021 Revoked April 2021	BMGF + DARPA's P3 Program [ADEPT]
Bebtelovimab	Abcellera +Eli Lilly	EUA Feb 2022	Bill & Melinda Gates Foundation

## Educational Institutions

## Non-Government Organizations

## Governmental Organizations

Vanderbilt  
UNC Chapel Hill  
Univ. Penn  
Univ TX Med Branch  
Dartmouth  
Emory  
Univ. Alabama  
Johns Hopkins  
Georgetown

Bill & Melinda Gates Foundation [BMGF]  
Scripps  
CEPI  
Wellcome Trust  
EcoHealth Alliance  
In-Q-Tel

JPEO-CBRN [ARMY]  
NIH/NIAID/FNIH  
DARPA  
DTRA  
BARDA  
ASPR/HHS  
NSF  
DHS-CWMD



# Government Funded Medical Countermeasures through Operation Warp Speed

[HTTPS://WWW.BECKERSHOSPITALREVIEW.COM/PHARMACY/13-DRUGMAKERS-CONTRACTED-BY-OPERATION-WARP-SPEED-IN-2020.HTML](https://www.beckershospitalreview.com/pharmacy/13-drugmakers-contracted-by-operation-warp-speed-in-2020.html)

1. **AstraZeneca** — In May, AstraZeneca signed a contract for \$1.2 billion to boost access to its COVID-19 vaccine. In October, the drugmaker signed a second contract for \$486 million for the U.S. to secure 100,000 doses of its experimental COVID-19 antibody drug and support clinical trials for the drug.
2. **Cytiva** — The Massachusetts drugmaker signed a contract in October for \$31 million to scale up production of materials needed to produce COVID-19 vaccines, such as liquid and dry powder cell culture media, cell culture buffers, bioreactors and mixer bags.
3. **Eli Lilly** — In October, Eli Lilly signed a \$375 million contract to supply 300,000 vials of its COVID-19 antibody drug, which was granted emergency authorization by the FDA in November. In early December, the drugmaker signed another \$812.5 million contract to supply 650,00 more doses of the drug.
4. **Emergent BioSolutions** — In June, Emergent BioSolutions signed a \$628 million contract to ramp up its contract development and manufacturing capabilities to expedite the delivery of COVID-19 vaccines.
5. **Fujifilm** — In July, Fujifilm signed a \$265 million contract to manufacture COVID-19 vaccines.
6. **Johnson & Johnson** — In August, Johnson & Johnson signed a more than \$1 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine if it is authorized.

**Eli Lilly: 1.1872B**

**AstraZeneca 1.68B**

**Emergent Bio: 628M**

**J&J: 1B**

**Moderna: 1.7B**

**Pfizer: 2B**

**GSK: 2.1B**

**Novavax: 1.6B**

7. **Moderna** — In August, Moderna signed a \$1.5 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine, if it is authorized.
8. **Novavax** — In July, Novavax signed a \$1.6 billion contract to supply the U.S. with 100 million doses of its COVID-19 vaccine, if it is authorized.
9. **Pfizer & BioNTech** — In July, Pfizer and BioNTech partnered to sign a \$1.95 billion contract to supply up to 600 million doses of its COVID-19 vaccine. Under the contract, the U.S. would receive 100 million doses of the vaccine with the opportunity to secure 500 million more doses, but the U.S. did not secure the additional doses.
10. **Regeneron** — In July, Regeneron signed a \$450 million contract to manufacture thousands of doses of its COVID-19 antibody cocktail, which was granted emergency authorization in November.
11. **Sanofi & GlaxoSmithKline** — In July, Sanofi and GlaxoSmithKline partnered to sign a \$2.1 billion contract for development of the drugmaker's COVID-19 vaccine as well as an initial supply of 100 million doses.



Recipient Name ▾	Start Date (Period of Performance) ▾	End Date (Period of Performance) ▾	Total Obligations to Date
RESILIENCE GOVERNMENT SERVIC...	3/20/2013	3/20/2023	\$276,824,216
RESILIENCE GOVERNMENT SERVIC...	8/17/2020	7/31/2021	\$92,024,000
RESILIENCE GOVERNMENT SERVIC...	1/4/2022	2/29/2028	\$86,818,905
RESILIENCE GOVERNMENT SERVIC...	9/28/2007	12/31/2011	\$14,898,363
RESILIENCE GOVERNMENT SERVIC...	9/9/2019	8/11/2024	\$14,408,703
RESILIENCE GOVERNMENT SERVIC...	8/15/2009	11/22/2013	\$12,927,512
RESILIENCE GOVERNMENT SERVIC...	9/30/2013	6/29/2021	\$10,604,966
RESILIENCE GOVERNMENT SERVIC...	3/22/2016	9/8/2021	\$6,821,012
RESILIENCE GOVERNMENT SERVIC...	6/11/2015	6/10/2017	\$6,193,052

Award ID ▾	Recipient Name ▾	Start Date (Period of Performance) ▾	End Date (Period of Performance) ▾	Total Obligations to Date
W911QY13C0010	RESILIENCE GOVERNMENT SERVIC...	3/20/2013	3/20/2023	\$276,824,216
W911QY20C0101	RESILIENCE GOVERNMENT SERVIC...	8/17/2020	7/31/2021	\$92,024,000
W911SR22F0014	RESILIENCE GOVERNMENT SERVIC...	1/4/2022	2/29/2028	\$86,818,905
HHSN272200700030C	RESILIENCE GOVERNMENT SERVIC...	9/28/2007	12/31/2011	\$14,898,363
75N93019C00057	RESILIENCE GOVERNMENT SERVIC...	9/9/2019	8/11/2024	\$14,408,703
HHSN272200900015C	RESILIENCE GOVERNMENT SERVIC...	8/15/2009	11/22/2013	\$12,927,512
HHSO10033001T	RESILIENCE GOVERNMENT SERVIC...	9/30/2013	6/29/2021	\$10,604,966
HHSN272201600009C	RESILIENCE GOVERNMENT SERVIC...	3/22/2016	9/8/2021	\$6,821,012
HHSO10033003T	RESILIENCE GOVERNMENT SERVIC...	6/11/2015	6/10/2017	\$6,193,052
W911SR22F0073	RESILIENCE GOVERNMENT SERVIC...	6/16/2022	2/28/2025	\$4,861,156
HHSO100201100047C	RESILIENCE GOVERNMENT SERVIC...	9/30/2011	12/15/2016	\$4,808,836
HHSO10033004T	RESILIENCE GOVERNMENT SERVIC...	6/11/2015	6/9/2018	\$4,761,491
W911SR23F0057	RESILIENCE GOVERNMENT SERVIC...	3/7/2023	1/5/2028	\$4,502,407
HHSO10033002T	RESILIENCE GOVERNMENT SERVIC...	11/18/2014	10/31/2017	\$3,251,785
HHSN266200500046P	RESILIENCE GOVERNMENT SERVIC...	9/29/2005	3/31/2010	\$3,044,549
HHSN271200577414C	RESILIENCE GOVERNMENT SERVIC...	9/15/2005	6/30/2009	\$892,166
W81XWH10C0245	RESILIENCE GOVERNMENT SERVIC...	9/1/2010	9/30/2013	\$853,062
HHSN27200002	RESILIENCE GOVERNMENT SERVIC...	8/7/2017	2/3/2020	\$816,039
W911QY19C0049	RESILIENCE GOVERNMENT SERVIC...	4/1/2019	7/31/2021	\$722,220
N0001406C0043	RESILIENCE GOVERNMENT SERVIC...	11/14/2005	11/13/2007	\$491,836
75N93023F00001	RESILIENCE GOVERNMENT SERVIC...	8/28/2023	5/30/2024	\$485,288
HHSD200200302362C	RESILIENCE GOVERNMENT SERVIC...	9/4/2003	3/14/2004	\$98,838
HHSN27200001	RESILIENCE GOVERNMENT SERVIC...	9/2/2016	8/31/2017	\$11,645

\$542,901,015



On Highergov, a government contract tracking website, shows the Definitive Contract W911QY13C0010 between the US ARMY & Resilience/Ology Bioservices. It not only shows the history of the contracts dated pre-pandmic, starting in 2013. It also shows that \$4,361,774 of the Definitive Contract was funded by COVID-19 emergency acts including the CARES Act.

HIGHERG

GOV

Federal

State | Local

EXPLORE

Search All

BUSINESS DEVELOPMENT

Opportunities

Contracts

Grants

Pursuit

Management

Pipelines

Pursuits

Activities

Partner

Finder

Government Buyers

Labor Pricing

MARKET INTELLIGENCE

Analysis

Awards

Vehicles

Contracts

Grants

Awardees

Search by Name or ID

More

Plans

Sign In

Free Trial

Search Awardees

Share

Claim

Export

Favorite

Notify

Resilience Government Services

UEI: GC2RFAZK8G64 • CAGE: 3GQS9

Overview

Analysis

Registration

People

Schedules

Vehicles 2

IDVs 5

Contracts 29

Subcontracts 25

Grants 7

Subgrants 2

Partners 2

Mentors

JVs

Overview

List

Text

Awardee Type

Parent

Federal Capability Statement

Pharmaceutical Research and Manufacturing

Quality Assurance Certifications

ISO-9000 Series

Website

https://www.resilience.com

Headquarters

Alachua, FL

United States

General Email

info@ologybio.com

Show Quick Stats (See Federal Award Analysis for Full Details)

Federal Award Analysis

Resilience Government Services federal award history

https://www.highergov.com/contract/W911QY13C0010/#people



# Definitive Contract W911QY13C0010 between the US ARMY & Resilience/Ology Bioservices.

HIGH

ERG

GOV

EXPLORE

Search All

BUSINESS DEVELOPMENT

Opportunities

Contracts

Grants

Pursuit

Management

Pipelines

Pursuits

Activities

Partner

Finder

Government Buyers

Labor Pricing

MARKET INTELLIGENCE

Analysis

Awards

Vehicles

Contracts

Grants

Awardees

Government

Agencies

People

Documents

Reference

Search by Name or ID

More Plans Sign In

Free Trial

Overview

Status

Announcement

Hierarchy

Timeline

Subs

Opps 3

History 83

People 4

Additional

Government Description

Awardee

Awarding Agency

Funding Agency

NAICS

PSC

Place of Performance

Pricing

Set Aside

Extent Competed

Est. Average FTE

Related Opportunity

MEDICAL COUNTERMEASURES ADVANCED DEVELOPMENT AND MANUFACTURING (MCM ADM) CAPABILITY

[Resilience Government Services](#)

[ACC Aberdeen Proving Ground \(APG\) \[DoD - USA - AMC - ACC\]](#)

[Joint PEO for Chemical, Biological, Radiological and Nuclear Defense \(JPEOCRBND\) \[DoD - USA - USAASC\]](#)

[325412 - Pharmaceutical Preparation Manufacturing](#)

[AE37 - R&D- Economic Growth: Manufacturing Technology \(Commercialized\)](#)

Alachua, FL 32615 United States

Cost Plus Fixed Fee

None

Full And Open Competition

225

[Medical Countermeasure Manufacturing Advanced Development Manufacturing \(MCM ADM\) Capability \(W911QY11R0023\)](#)

Analysis Notes

COVID-19

\$4,361,774 (2%) percent of this Definitive Contract was funded by COVID-19 emergency acts including the CARES Act.

Amendment

Since initial award the Potential End Date has been extended from 03/19/23 to 10/31/23 and the Potential Award value has decreased 13% from \$420,288,907 to \$366,290,602.

Unrealized Backlog

This Definitive Contract is complete with \$5,466,762 of funded backlog and \$89,466,386 of unfunded backlog unused, which is typically due to unexercised options.

DOD Announcements

Sep 2014:

https://www.highergov.com/contract/W911QY13C0010/#people

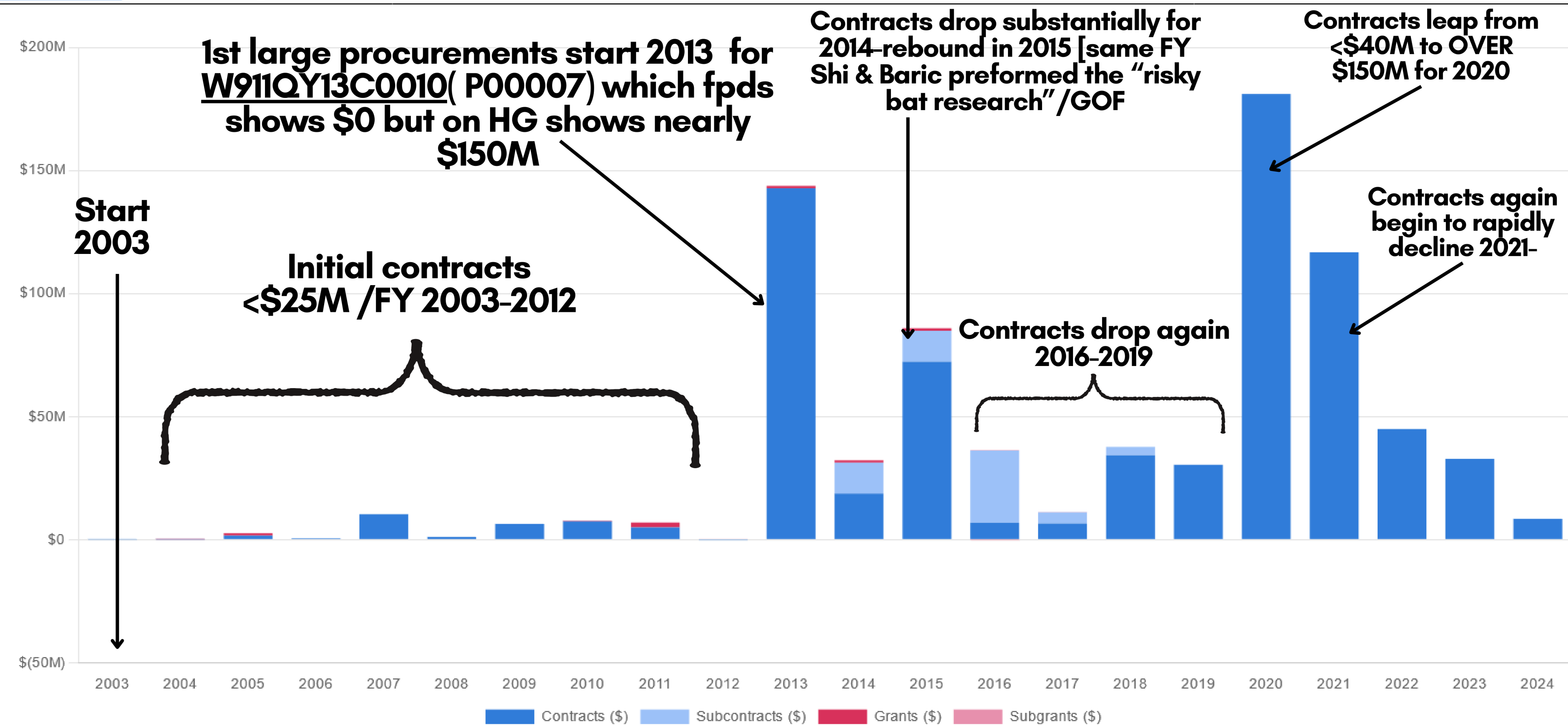


# CARES ACT & OPERATION WARP SPEED

- The CARES Act provided funding for Operation Warp Speed.
- Operation Warp Speed was initially funded with about \$10 billion from the CARES Act (Coronavirus Aid, Relief, and Economic Security) passed by the United States Congress on March 27, 2020.
- Congress directed almost \$10 billion to Operation Warp Speed through supplemental funding, including the CARES Act. This included more than \$6.5 billion designated for countermeasure development through BARDA and \$3 billion for NIH research.
- In searching for funding, the Operation Warp Speed team pulled \$10 billion from the CARES Act, which was there thanks to Treasury Secretary Steven Mnuchin, who had added extra money to the Strategic National Stockpile in order to create a slush fund.

In summary, the CARES Act provided a significant portion of the initial funding for Operation Warp Speed's efforts to accelerate the development and production of COVID-19 vaccines and treatments. **The Act allocated over \$10 billion specifically for this purpose.**







# Definitive Contract W91QY13C0010 between the US ARMY & Resilience/Ology Bioservices.

Agency Detail		Legislative	
Awarding Office	W911QY W6QK ACC-APG NATICK	Legislative Mandates	Materials, Supplies, Articles & Equipment
Funding Office	W56XNH	Performance District	FL-03
Created By	dan.l.adams2.civ@army.mil	Senators	Marco Rubio Rick Scott
Last Modified By	dan.l.adams2.civ@army.mil	Representative	Katherine Cammack
Approved By	dan.l.adams2.civ@army.mil		

Budget Funding				
Federal Account	Budget Subfunction	Object Class	Total	Percentage
Research, Development, Test, and Evaluation, Defense-Wide (097-0400)	Department of Defense-Military	Research and development contracts (25.5)	\$19,910,440	89%
Research, Development, Test, and Evaluation, Defense-Wide (097-0400)	Department of Defense-Military	Other services from non-Federal sources (25.2)	\$2,464,858	11%

**Definitive Contract W91QY13C0010 between the US ARMY & Resilience/Ology Bioservices.**  
*\*A definitive contract is a mutually binding legal relationship that obligates the government to an expenditure of appropriated funds.\**  
<https://www.highergov.com/contract/W911QY13C0010/#people>



On the Federal Procurement Data System [fpds.gov], a government owned and operated contract tracking program it shows the Definitive Contract W911QY13C0010. Involved the Defense Contract Management Agency [DCMA], the US ARMY & the record shows : **Resilience Government Services [4 contracts]** **Ology Bioservices [28 contracts]** & **Nanotherapeutics [51 contracts]** For a total of 83 contracts between the entity called "Resilience" and the DoD.

Type one or more keywords you would like to search on:  
W911QY13C0010

GoClearAdvanced Search

ContractsICDRecovery

To submit comments, please [click here](#)

Search took 0.282 seconds

Result Page: 123Next

PDFCSVATOM0.3

You must click [here](#) for very important D&B information.

Top 10: Department Full Name  
DEPT OF DEFENSE (83)

Top 10: Contracting Agency Name  
DEPT OF THE ARMY (82)  
DEFENSE CONTRACT MANAGEMENT AGENCY (DCMA) (1)

Top 10: Full Legal Business Name  
NANOTHERAPEUTICS, INC. (51)  
OLOGY BIOSERVICES, INC (28)  
RESILIENCE GOVERNMENT SERVICES, INC. (4)

Top 10: Treasury Account Symbol  
970400 (83)

List Of Contract Actions Matching Your Criteria

Results 1 - 30 of 83 as of May 3, 2024 3:20:27 PM

Award ID (Mod#):	W911QY13C0010 ( P00007 ) (View)	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	NANOTHERAPEUTICS, INC.	Contracting Agency:	DEPT OF THE ARMY
Date Signed:	August 26, 2013	Action Obligation:	\$0
Referenced IDV:		Contracting Office:	W6QK ACC-APG NATICK
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING ( 325412 )	PSC (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) ( AE37 )
Entity City:	ALACHUA	Unique Entity ID:	GC2RFAZK8G64
Entity State:	FL	Ultimate Parent Unique Entity ID:	GC2RFAZK8G64
Entity ZIP:	326156832	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS INC.
Cage Code:			

Award ID (Mod#):	W911QY13C0010 ( P00031 ) (View)	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	NANOTHERAPEUTICS, INC.	Contracting Agency:	DEPT OF THE ARMY
Date Signed:	March 29, 2017	Action Obligation:	\$2,808,778.83
Referenced IDV:		Contracting Office:	W6QK ACC-APG NATICK
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING ( 325412 )	PSC (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) ( AE37 )
Entity City:	ALACHUA	Unique Entity ID:	GC2RFAZK8G64
Entity State:	FL	Ultimate Parent Unique Entity ID:	GC2RFAZK8G64

Search Criteria ?

To remove the criteria or a portion of the search criteria click the button next to each search level.

X W911QY13C0010

Sort By ?

This section allows the user to sort the existing list of contracts by various fields within the contract. For example you can sort the existing list of contracts by Date Signed or Contract Type. Click on the appropriate field to Sort By. Only one Sort can be conducted at a time.

Sort Order: Descending v

Relevance  
[Contract Type](#)  
[Agency Code](#)  
[Agency Full Name](#)  
[Date Signed](#)  
[Contracting Agency ID](#)  
[Contracting Agency Name](#)  
[Department Full Name](#)  
[Action Obligation \(\\$\)](#)  
[NAICS](#)

<https://www.fpds.gov/ezsearch/fpdsportal?indexName=awardfull&templateName=1.5.3&s=ICD&q=W911QY13C0010&x=0&y=0>



# According to HIGHERGOV, as detailed in the

Sep 2014:

Nanotherapeutics, Inc.,\* Alachua, Florida was awarded a \$9,647,917 modification (P00018 ) to contract W911QY-13-C-0010 for Medical Countermeasures (MCM) Advanced Development and Manufacturing (ADM) capability for rapid development of countermeasures against chemical, biological, radiological, and nuclear attacks and outbreaks of naturally occurring and genetically engineered infectious diseases. Fiscal 2014 research, development, testing, and evaluation funds in the amount of \$9,647,917 were obligated at the time of the award. Estimated completion date is March 19, 2015. Work will be performed in Alachua, Florida. Army Contracting Command, Natick, Massachusetts is the contracting activity. (Awarded Sept. 28, 2014).

May 2015: Nanotherapeutics Inc.,\* Alachua, Florida, was awarded a \$43,249,906 modification (P00020) to contract W911QY-13-C-0010 for research and development of medical countermeasures and their manufacture to counter a chemical, biological, radiological, nuclear and explosives attack against military and civilian targets. Work will be performed in Alachua, Florida, with an estimated completion date of Aug. 15, 2016. Fiscal 2014 research, development, testing, and evaluation funds in the amount of \$4,324,906 were obligated at the time of the award. Army Contracting Command, Natick, Massachusetts, is the contracting activity.

Sep 2019: Ology Bioservices Inc.,\* Alachua, Florida, was awarded a \$10,870,944 modification (P00054) to contract W911QY-13-C-0010 to establish, commission and support an agile and flexible advanced development and manufacturing capability. Work will be performed in Alachua, Florida, with an estimated completion date of March 19, 2023. Fiscal 2020 research, development, test and evaluation funds in the amount of \$7,845,964 were obligated at the time of the award. U.S. Army Contracting Command, Aberdeen Proving Ground, Maryland, is the contracting activity.

Dec 2019: Ology Bioservices Inc., Alachua, Florida, was awarded an \$8,553,208 modification (P00058) to contract W911QY-13-C-0010 to support the Medical Countermeasures Advanced Development and Manufacturing Center Sustainment by maintaining the Advanced Development and Manufacturing facility in a state of readiness and operational availability to develop, test and/or manufacture medical countermeasures. Work will be performed in Alachua, Florida, with an estimated completion date of March 19, 2023. Fiscal 2021 research, development, test and evaluation, defense-wide funds in the amount of \$8,553,208 were obligated at the time of the award. U.S. Army Contracting Command, Aberdeen Proving Ground, Natick Division, Natick, Massachusetts, is the contracting activity.

<https://www.highergov.com/contract/W911QY13C0010/#people>



Aug  
2013

Award ID (Mod#):	<a href="#">WS11QY13C0010</a> (P00007) ( <a href="#">View</a> )	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>	Contracting Agency:	<a href="#">DEPT OF THE ARMY</a>
Date Signed:	August 26, 2013	Action Obligation:	\$0
Referenced IDV:		Contracting Office:	<a href="#">WS9K.ACC-APS.NATICK</a>
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING ( <a href="#">325412</a> )	P&C (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) ( <a href="#">AE37</a> )
Entity City:	ALACHUA	Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity State:	FL	Ultimate Parent Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity ZIP:	<a href="#">326156932</a>	Ultimate Parent Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>
Cage Code:			

\$0

Mar  
2017

Award ID (Mod#):	<a href="#">WS11QY13C0010</a> (P00031) ( <a href="#">View</a> )	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>	Contracting Agency:	<a href="#">DEPT OF THE ARMY</a>
Date Signed:	March 29, 2017	Action Obligation:	\$2,808,778.83
Referenced IDV:		Contracting Office:	<a href="#">WS9K.ACC-APS.NATICK</a>
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING ( <a href="#">325412</a> )	P&C (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) ( <a href="#">AE37</a> )
Entity City:	ALACHUA	Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity State:	FL	Ultimate Parent Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity ZIP:	<a href="#">326156726</a>	Ultimate Parent Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>
Cage Code:	<a href="#">35Q88</a>		

\$2.8M

Oct  
2017

Award ID (Mod#):	<a href="#">WS11QY13C0010</a> (P00038) ( <a href="#">View</a> )	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>	Contracting Agency:	<a href="#">DEPT OF THE ARMY</a>
Date Signed:	December 06, 2017	Action Obligation:	\$2,500,000
Referenced IDV:		Contracting Office:	<a href="#">WS9K.ACC-APS.NATICK</a>
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING ( <a href="#">325412</a> )	P&C (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) ( <a href="#">AE37</a> )
Entity City:	ALACHUA	Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity State:	FL	Ultimate Parent Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity ZIP:	<a href="#">326156726</a>	Ultimate Parent Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>
Cage Code:	<a href="#">35Q88</a>		

\$2.5M

Jun  
2018

Award ID (Mod#):	<a href="#">WS11QY13C0010</a> (P00043) ( <a href="#">View</a> )	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>	Contracting Agency:	<a href="#">DEPT OF THE ARMY</a>
Date Signed:	June 12, 2018	Action Obligation:	\$2,000,000
Referenced IDV:		Contracting Office:	<a href="#">WS9K.ACC-APS.NATICK</a>
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING ( <a href="#">325412</a> )	P&C (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) ( <a href="#">AE37</a> )
Entity City:	ALACHUA	Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity State:	FL	Ultimate Parent Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity ZIP:	<a href="#">326156726</a>	Ultimate Parent Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>
Cage Code:	<a href="#">35Q88</a>		

\$2M

Sept  
2019

Award ID (Mod#):	<a href="#">WS11QY13C0010</a> (P00054) ( <a href="#">View</a> )	Award Type:	DEFINITIVE CONTRACT
Legal Business Name:	<a href="#">QLOGY BIOSERVICES, INC.</a>	Contracting Agency:	<a href="#">DEPT OF THE ARMY</a>
Date Signed:	September 10, 2019	Action Obligation:	\$7,845,964.34
Referenced IDV:		Contracting Office:	<a href="#">WS9K.ACC-APS.NATICK</a>
NAICS (Code):	PHARMACEUTICAL PREPARATION MANUFACTURING ( <a href="#">325412</a> )	P&C (Code):	R&D- ECONOMIC GROWTH: MANUFACTURING TECHNOLOGY (COMMERCIALIZED) ( <a href="#">AE37</a> )
Entity City:	ALACHUA	Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity State:	FL	Ultimate Parent Unique Entity ID:	<a href="#">GC2REAZK3G64</a>
Entity ZIP:	<a href="#">326156726</a>	Ultimate Parent Legal Business Name:	<a href="#">NANOTHERAPEUTICS, INC.</a>
Cage Code:	<a href="#">35Q88</a>		

\$7.8M



Transaction Information			
Award Type:	Definitive Contract	Prepared Date:	03/28/2019 16:11:39
Award Status:	Final	Last Modified Date:	03/28/2019 16:11:43
Closed Status:	No	Closed Status Date:	
		Approved Date:	03/28/2019 16:11:43
Prepared User:	LAWRENCE.MIZE.W911QY@US.ARMY.MIL		
Last Modified User:	LAWRENCE.MIZE.W911QY@US.ARMY.MIL		
Closed By:			
Approved By:	LAWRENCE.MIZE.W911QY@US.ARMY.MIL		
Document Information			
Award ID:	9700	Procurement Identifier	W911QY13C0010
Referenced IDV ID:		Modification No	P00051
Reason For Modification:	EXERCISE AN OPTION		
Solicitation ID:	W911QY11R0023		
Treasury Account Symbol:	97	Agency Main Sub Identifier Account	0400
		Initiative	Select One
Dates		Amounts	
Date Signed (mm/dd/yyyy) :	03/28/2019	Action Obligation:	Current
Period of Performance Start Date (mm/dd/yyyy) :	03/29/2019	Base And Exercised Options Value:	\$7,031,994.58
Completion Date (mm/dd/yyyy) :	10/31/2020	Base and All Options Value (Total Contract Value):	\$276,824,216.28
Est. Ultimate Completion Date (mm/dd/yyyy) :	10/31/2023		\$12,379,190.00
Solicitation Date (mm/dd/yyyy) :			-\$26,139,593.00
		Fee Paid for Use of IDV:	\$0.00
Purchaser Information			
Contracting Office Agency ID:	2100	Contracting Office Agency Name:	DEPT OF THE ARMY
Contracting Office ID:	W911QY	Contracting Office Name:	W6QK ACC-APG NATICK
Funding Agency ID:	2100	Funding Agency Name:	DEPT OF THE ARMY
Funding Office ID:	W56XNH	Funding Office Name:	W6DZ JPMO CBD JPMO MCS (06)
Foreign Funding:	Not Applicable		
Entity Information			

W911QY

W911QY refers to a series of contracts and solicitations related to the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND).The key details are:W911QY-20-C-0119 is a contract awarded to AstraZeneca Pharmaceuticals LP for \$855 million to manufacture medical countermeasures. W911QY-18-D-0232 to W911QY-18-D-0252 are a set of multiple award Indefinite Delivery Indefinite Quantity (IDIQ) contracts for the JE-OPETS program, which provides Chemical, Biological, Radiological, and Nuclear (CBRN)-related program management and Systems Engineering and Technical Assistance (SETA) support.



Dates		Amounts	
Date Signed (mm/dd/yyyy) :	03/28/2019		
Period of Performance Start Date (mm/dd/yyyy) :	03/29/2019	Action Obligation:	Current: \$7,031,994.58 Total: \$276,824,216.28
Completion Date (mm/dd/yyyy) :	10/31/2020	Base And Exercised Options Value:	\$12,379,190.00 \$282,290,978.35
Est. Ultimate Completion Date (mm/dd/yyyy) :	10/31/2023	Base and All Options Value (Total Contract Value):	-\$26,139,593.00 \$366,290,602.35
Solicitation Date (mm/dd/yyyy) :		Fee Paid for Use of IDV:	\$0.00
<b>Purchaser Information</b>			
Contracting Office Agency ID:	2100	Contracting Office Agency Name:	DEPT OF THE ARMY
Contracting Office ID:	W911QY	Contracting Office Name:	W6QK ACC-APG NATICK
Funding Agency ID:	2100	Funding Agency Name:	DEPT OF THE ARMY
Funding Office ID:	W56XNH	Funding Office Name:	W6DZ JPMO CBD JPMO MCS (06)
Foreign Funding:	Not Applicable		
<b>Entity Information</b>			

Funding Office Name:

**W6DZ JPMO CBD JPMO MCS**

W911QY

**W6DZ JPMO CBD JPMO MCS (06) refers to the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), which is the funding office for several contracts related to chemical and biological defense programs.**

W6DZ JPMO CBD JPMO MCS (06) is listed as the funding office for multiple contracts with Eli Lilly and Company totaling over \$4.6 billion & for contract W911QY21C0016 with Eli Lilly and Company..

W6DZ JPMO CBD JPMO MCS (06) is mentioned as the parent award details for contract W911SR23F7017 with MURTECH, INC

It is also listed as the funding department for contract W15QKN21C0003 related to COVID-19 contracts.

W6DZ JPMO CBD JPMO MCS (06) is the funding office code for the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, which oversees various contracts **related to chemical and biological defense programs**



REVIEW

# Zika Virus: Medical Countermeasure Development Challenges

Robert W. Malone<sup>1,2\*</sup>, Jane Homan<sup>3</sup>, Michael V. Callahan<sup>4</sup>, Jill Glasspool-Malone<sup>1,2</sup>, Lambodhar Damodaran<sup>5</sup>, Adriano De Bernardi Schneider<sup>5</sup>, Rebecca Zimler<sup>6</sup>, James Talton<sup>7</sup>, Ronald R. Cobb<sup>7</sup>, Ivan Ruzic<sup>8</sup>, Julie Smith-Gagen<sup>9</sup>, Daniel Janies<sup>5†</sup>, James Wilson<sup>10‡</sup>, Zika Response Working Group

**1** RW Malone MD LLC, Scottsville, Virginia, United States of America, **2** Class of 2016, Harvard Medical School Global Clinical Scholars Research Training Program, Boston, Massachusetts, United States of America, **3** ioGenetics, Madison, Wisconsin, United States of America, **4** Department of Medicine, Division of Infectious Diseases, Massachusetts General Hospital, Boston, Massachusetts, United States of America, **5** Department of Bioinformatics and Genomics, University of North Carolina at Charlotte, Charlotte, North Carolina, United States of America, **6** University of Florida, Department of Entomology and Nematology, Florida Medical Entomology Laboratory, Vero Beach, Florida, United States of America, **7** Nanotherapeutics, NANO-ADM Advanced Development and Manufacturing Center, Alachua, Florida, United States of America, **8** Analytical Outcomes, Washington Crossing, Pennsylvania, United States of America, **9** School of Community Health Sciences, University of Nevada, Reno, Nevada, United States of America, **10** Nevada Center for Infectious Disease Forecasting, University of Nevada, Reno, Nevada, United States of America

† The senior authors contributed equally to this work.

\* [RWMaloneMD@gmail.com](mailto:RWMaloneMD@gmail.com)

## Abstract

## Introduction



**OPEN ACCESS**

**Citation:** Malone RW, Homan J, Callahan MV, Glasspool-Malone J, Damodaran L, Schneider ADB, et al. (2016) Zika Virus: Medical Countermeasure Development Challenges. PLoS Negl Trop Dis 10(3): e0004530. doi:10.1371/journal.pntd.0004530

**Editor:** Rebekah Crockett Kading, Colorado State University, UNITED STATES



**This 2016 paper, although it does not appear to be directly related to C19 in fact is. It is important to C19 for 5 reasons.**

1. The Zika Virus research in 2016 helped the VRC in their work leading to their creation of the **C19 Vaccine w/Moderna** [2017]
2. A listed author is **Michael Callahan, "DARPA's Man in Wuhan"** whom fellow author, Robert Malone, claimed is CIA and that Callahan is "a very skilled liar."
3. Dr. Robert Malone [contractee of the DTRA] **inventor of the mRNA "vaccine"** platform & his wife Dr. Jill Glasspool-Malone are authors.
4. Two employees [**Talton+Cobb**] of **Nanotherapeutics [Resilience/Ology]** & acknowledges the JPEO-CBRND's ownership by identifying the DoD's name for the facility, NANO-ADM as the facility for Nanotherapeutics.. **The Funding itself shows it was on the dime of the Aberdeen Proving Grounds, NATICK, of the US ARMY, the SAME exact command** that ALL the C19 "vaccines" were contracted through.
5. Three of 13 authors are representing **UNC Chapel Hill**, who was undoubtedly the home to the world's most advanced coronavirus research[ i.e Ralph Baric/Gillings School of Public health]

**OPEN ACCESS**

**Citation:** Malone RW, Homan J, Callahan MV, Glasspool-Malone J, Damodaran L, Schneider ADB, et al. (2016) Zika Virus: Medical Countermeasure Development Challenges. PLoS Negl Trop Dis 10(3): e0004530. doi:10.1371/journal.pntd.0004530

**Editor:** Rebekah Crockett Kading, Colorado State University, UNITED STATES

**Published:** March 2, 2016

**Copyright:** © 2016 Malone et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

**Funding:** The authors received no specific funding support for this publication. The NANO-ADM has been funded in whole or in part with Federal funds from the US Army Contracting Command – APG, Natick Contracting Division, Department of Defense under Contract No. W911QY-13-C-0010. Research reported in this publication was supported by a UNC Research Opportunities Initiative grant to UNC Charlotte, NC State University, and UNC-Chapel Hill. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing Interests:** I have read the journal's policy and the authors of this manuscript have the following competing interests: RWM and JGM are employees and equity holders in RW Malone MD LLC. JH is an

† The senior authors contributed equally to this work.  
\* [RWMaloneMD@gmail.com](mailto:RWMaloneMD@gmail.com)

## Abstract

## Introduction

Reports of high rates of primary microcephaly and Guillain-Barré syndrome associated with Zika virus infection in French Polynesia and Brazil have raised concerns that the virus circulating in these regions is a rapidly developing neuropathic, teratogenic, emerging infectious public health threat. There are no licensed medical countermeasures (vaccines, therapies or preventive drugs) available for Zika virus infection and disease. The Pan American Health Organization (PAHO) predicts that Zika virus will continue to spread and eventually reach all countries and territories in the Americas with endemic *Aedes* mosquitoes. This paper reviews the status of the Zika virus outbreak, including medical countermeasure options, with a focus on how the epidemiology, insect vectors, neuropathology, virology and immunology inform options and strategies available for medical countermeasure development and deployment.

## Methods

Multiple information sources were employed to support the review. These included publicly available literature, patents, official communications, English and Lusophone lay press. Online surveys were distributed to physicians in the US, Mexico and Argentina and responses analyzed. Computational epitope analysis as well as infectious disease outbreak modeling and forecasting were implemented. Field observations in Brazil were compiled and interviews conducted with public health officials.



# W6DZ JPMO CBD JPMO MCS

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30				1. REQUISITION NUMBER 00H1500611-0001		PAGE 1 OF 44	
2. CONTRACT NO. W911QY20C0101		3. AWARD EFFECTIVE DATE 17-Aug-2020		4. ORDER NUMBER		5. SOLICITATION NUMBER	
7. FOR SOLICITATION INFORMATION CALL:		a. NAME				b. TELEPHONE NUMBER (No Collect Calls)	
9. ISSUED BY WSOK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011 TEL: FAX: 508-233-5700		CODE W911QY		10. THIS ACQUISITION IS <input checked="" type="checkbox"/> UNRESTRICTED OR <input checked="" type="checkbox"/> SET ASIDE: 100% FOR: <input checked="" type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> WOMEN-OWNED SMALL BUSINESS (WOSB) <input type="checkbox"/> HUBZONE SMALL BUSINESS <input type="checkbox"/> ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM <input type="checkbox"/> EDWOSB NAICS: 325412 <input type="checkbox"/> SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS <input type="checkbox"/> 8(A) SIZE STANDARD: 1,250			
11. DELIVERY FOR FOR DESTINATION UNLESS BLOCK IS MARKED <input type="checkbox"/> SEE SCHEDULE		12. DISCOUNT TERMS Net 30 Days		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) <input type="checkbox"/>		13b. RATING	
15. DELIVER TO BARDA BIOLOGICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20004		CODE W508NH		16. ADMINISTERED BY  SEE ITEM 9			
17a. CONTRACTOR/ OFFEROR OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13000 NW NANO COURT ALACHUA FL 32615-8726 TELEPHONE NO. 386-482-9663		CODE 3GQS9		FACILITY CODE 3GQS9		18a. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFA S-INDY VP GREBS 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800	
17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER <input type="checkbox"/>		18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a. UNLESS BLOCK BELOW IS CHECKED <input checked="" type="checkbox"/> SEE ADDENDUM					
19. ITEM NO.	20. SCHEDULE OF SUPPLIES/ SERVICES			21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
SEE SCHEDULE							
25. ACCOUNTING AND APPROPRIATION DATA See Schedule					26. TOTAL AWARD AMOUNT (For Govt. Use Only) (b) (4)		
27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3, 52.212-5 ARE ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED							
27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4, FAR 52.212-5 IS ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED							
28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED. REF: Resumption of SARS-CoV-2 R				29. AWARD OF CONTRACT: REF. OFFER DATED 31-Jul-2020. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: SEE SCHEDULE			
30a. SIGNATURE OF OFFEROR/CONTRACTOR (b) (6)				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) (b) (6)			
30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT) (b) (6)		30c. DATE SIGNED 08/17/20		31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT) (b) (6) CONTRACTING OFFICER TEL: (b) (6) K904111 (b) (6)		31c. DATE SIGNED 17-Aug-2020	

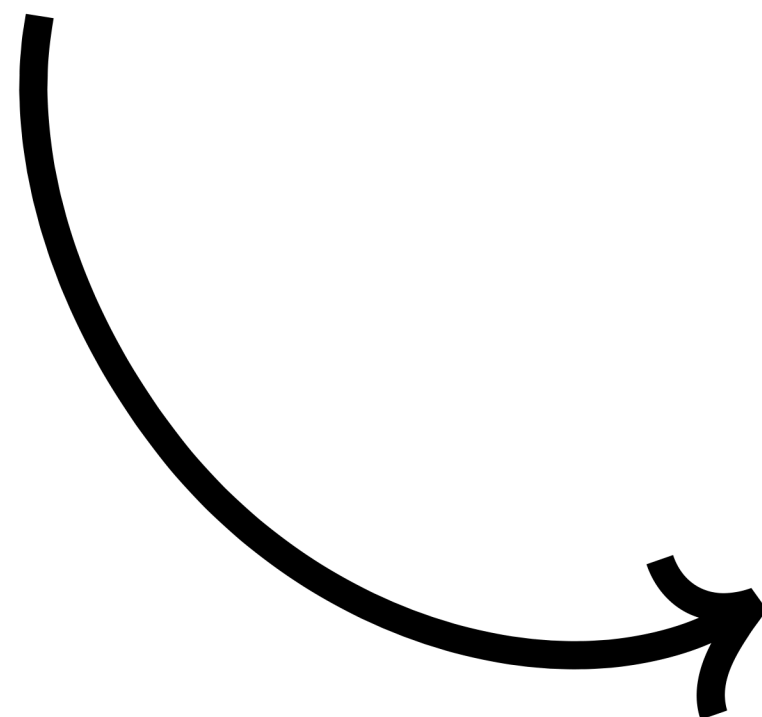
AUTHORIZED FOR LOCAL REPRODUCTION  
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)  
Prescribed by GSA - FAR (48 CFR) 53.212

# ADM Report 2018

## BARDA + JPEO-CBRND

### ASPR + DOD



A whole of government approach to the ADMs



**ADVANCED DEVELOPMENT  
AND MANUFACTURING  
TIGER TEAM FINDINGS**



**Michael Angelastro**  
Director (acting)  
Pharmaceutical Countermeasures Infrastructure (PCI)  
ASPR/BARDA  
HHS

**Timothy Belski**  
Director  
Advanced Development & Manufacturing Capabilities (ADMc)  
Medical Countermeasure Systems (MCS)  
Joint Project Management Office  
DoD

[https://medicalcountermeasures.gov/BARDA/Documents/BID2018\\_Presentations/WHOLE%20GOV%20APP%20ADM.pdf](https://medicalcountermeasures.gov/BARDA/Documents/BID2018_Presentations/WHOLE%20GOV%20APP%20ADM.pdf)



## HHS CIADM REQUIREMENT

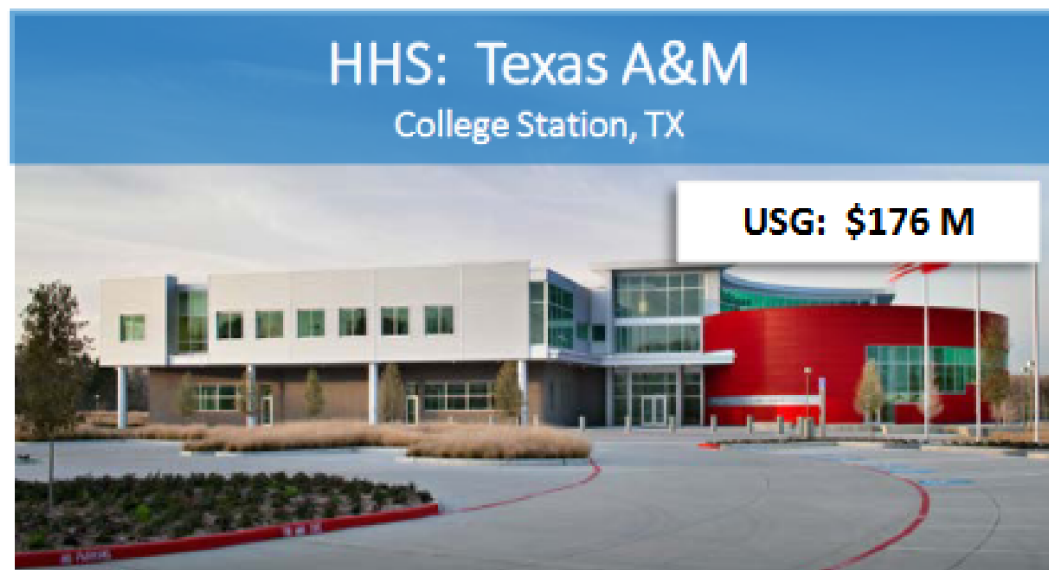
### Centers for Innovation in Advanced Development and Manufacturing



#### Objectives

- Construct new or retrofitted facilities utilizing state-of-the-art flexible manufacturing approaches;
- Provide core services for the advanced development and manufacturing of CBRN biopharmaceutical countermeasures supported by the U.S. Government;
- Provide U.S.-based surge capacity to respond to an emerging infectious disease, pandemic influenza, and currently known or unknown threats; and
- Biopharmaceutical oriented workforce development through training programs aligned with current regulatory guidelines.

# HHS AND DOD ADM INVESTMENTS



Total Base Period Capital Investment: \$602 M



ADVANCED DEVELOPMENT  
AND MANUFACTURING  
TIGER TEAM

5

[https://medicalcountermeasures.gov/BARDA/Documents/BID2018\\_Presentations/WHOLE%20GOV%20APP%20ADM.pdf](https://medicalcountermeasures.gov/BARDA/Documents/BID2018_Presentations/WHOLE%20GOV%20APP%20ADM.pdf)



# ADM TIGER TEAM

## ACTIVITIES OVERVIEW

### ADM Tiger Team Established

Michael Angelastro, BARDA Co-Lead  
Timothy Belski, DoD Co-Lead

Keith Wells, Ph.D., BARDA SME  
Mark Michalik, BARDA SME  
Jean Hu-Primmer, FDA

Chris Southworth, DoD ADMC Support  
Patricia Haigwood, BARDA CIADM Support  
Barry Sayer, DoD ADMC Support

### ADM Assessment Activities

#### Data Gathering

Discussions and Site Visits

- Emergent
- Ology
- Texas A&M
- Seqirus

#### Stakeholder Input / Landscape Analysis

- JVAP, JSTO
- PRISM
- DARPA
- SIP
- Biodefense Blue Ribbon Panel
- National Academies
- ASPR
- ASH
- WRAIR

#### Assessment of Key Inputs and Actions

#### Synthesis of Barriers and Potential Solutions

Lists are not all inclusive

!?



ADVANCED DEVELOPMENT  
AND MANUFACTURING  
TIGER TEAM

12

# PARTNERSHIP GOALS

ADM MODEL	PARTNERSHIP APPROACH
<ul style="list-style-type: none"><li>• ADM facilities worked independently</li></ul>	<ul style="list-style-type: none"><li>• HHS and DOD will collaborate, create a 'whole of government approach'</li></ul>
<ul style="list-style-type: none"><li>• Funded industry partners were required to use ADM facilities for certain efforts</li></ul>	<ul style="list-style-type: none"><li>• HHS and DOD will work with industry to provide incentives to use ADM facilities</li></ul>
<ul style="list-style-type: none"><li>• Any IP and legal challenges were left to the ADM facilities and industry partners to work out</li></ul>	<ul style="list-style-type: none"><li>• All challenges (IP, legal issues, etc) will be worked on as a team with support from USG</li></ul>
<ul style="list-style-type: none"><li>• Product-focused</li></ul>	<ul style="list-style-type: none"><li>• The ADM facilities will have the capability to handle a broad array of threats with proven technologies such as cell lines, adjuvants, and monoclonal antibody technologies</li></ul>
<ul style="list-style-type: none"><li>• Specific, often rigid, funding vehicle</li></ul>	<ul style="list-style-type: none"><li>• Exploring alternate funding vehicles for ease of contracting for industry</li></ul>
<ul style="list-style-type: none"><li>• Challenges due to ADM facilities being constructed, staffed, standing up</li></ul>	<ul style="list-style-type: none"><li>• Construction of all ADM facilities are complete and staffed with experienced manufacturing personal</li></ul>





Home

News

## Nanotherapeutics Breaks Ground on New Facility in Alachua

Posted by Business Report of North Central Florida | Date: October 23, 2013 | in: News



Nanotherapeutics, Inc., a biopharmaceutical company out of Alachua that began as a startup in the UF Sid Martin Biotech Incubator, held a groundbreaking to celebrate the start of construction on its new facility on Wednesday. In attendance were dozens of business and local government representatives, as well as Florida Gov. Rick Scott.

The new 165,000-square-foot facility at 13200 NW Nano Court — in Progress Corporate Park — is expected to be completed and occupied by March 2015. The new construction is the result of a Department of Defense contract worth \$135 million with the aim to reduce the overall time and cost associated with the development and manufacturing of medical countermeasures against chemical, biological, radiological and nuclear attacks and outbreaks of naturally occurring and genetically engineered infectious diseases.

The new facility will officially be called the Nanotherapeutics Advanced Development and Manufacturing Center (NANO-ADM). Over time, the ADM will offer its services and capabilities in medical countermeasures to broader customer bases, including the U.S. Department of Health and Human Services, as well as industry. NANO-ADM will provide flexible, single-use, disposable equipment that will fit national security requirements for the Medical Counter Measures program.

# 2013



Thermo Fisher Scientific Joins Momentum Labs as Founding Sponsor of New Biotech Hub in Alachua

Statement of

Bryce H. P. Mendez  
Specialist in Defense Health Care Policy

Before

Committee on Armed Services  
Subcommittee on Personnel  
U.S. Senate

Hearing on

**“Department of Defense’s efforts to ensure  
servicemembers’ access to safe, high-quality  
pharmaceuticals”**

April 30, 2024

Congressional Research Service  
<https://crsreports.congress.gov>  
TE10099

2013

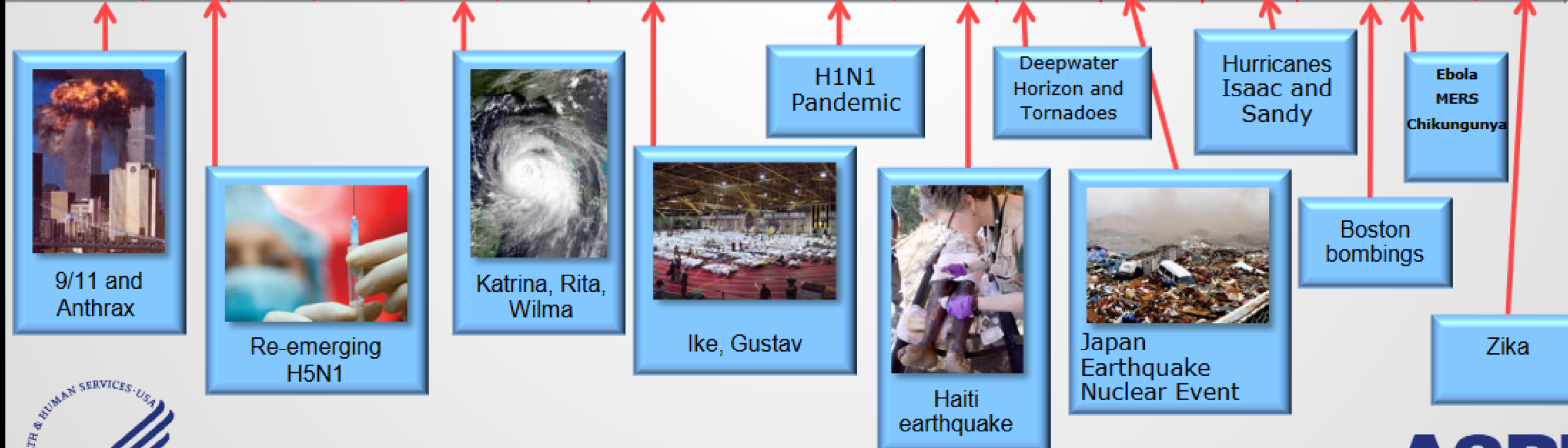
## DOD Advanced Development and Manufacturing Biopharmaceutical Facility

The Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), an office under the Chemical and Biological Defense Program, administers the DOD Advanced Development and Manufacturing (ADM) Biopharmaceutical Facility located in Alachua, FL.<sup>31</sup> The ADM facility is a contractor-owned, contractor-operated facility that provides DOD with an “enduring capability and infrastructure” to meet military medical requirements and the “capability for agile and flexible advanced development and manufacturing” of medical countermeasures.<sup>32</sup> In December 2010, then-Assistant to the President for Homeland Security, John O. Brennan, transmitted a memorandum calling for the Secretary of Defense to “establish agile and flexible advanced development and manufacturing capabilities to support the development, licensure, and production of medical countermeasures.”<sup>33</sup> In response to this directive, on March 21, 2013, Army Contracting Command awarded a \$135.8 million contract to then-Nanotherapeutics Inc. to build and operate the ADM facility, which provides DOD with “priority access” to the contractor’s manufacturing capabilities in order to “produce medical countermeasures more quickly and more effectively than other drug makers.”<sup>34</sup> According to JPEO-CBRND, the ADM facility is compliant with cGMP regulations, certified for biosafety level-3 (BSL-3) research, and has developed biologics to address COVID-19, Botulism neurotoxin, and other health threats.<sup>35</sup>



# Response: A series of Policies track after Events

## POLICY



## EVENTS



---

DC, July 25, 2017, at <https://www.ausa.org/sites/default/files/army-medical-eckels.pdf>; and WRAIR, “Pilot Bioproduction Facility (PBF),” fact sheet, November 2022, at [https://wrair.health.mil/Portals/87/Documents/PBF%20Handout%202022\\_Updated\\_21NOV22\\_final.pdf](https://wrair.health.mil/Portals/87/Documents/PBF%20Handout%202022_Updated_21NOV22_final.pdf).

<sup>29</sup> Ibid; and WRAIR briefing and discussions with CRS, October 2023.

<sup>30</sup> Ibid.

<sup>31</sup> Kelly Burkhalter and Chris Southworth, “Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience,” *JPEO-CBRND News*, December 5, 2023, at <https://www.jpeocbrnd.osd.mil/Media/News/Article/3607443/enduring-capability-jpeo-cbrnd-evolves-publicprivate-partnership-with-national/#:~:text=Located%20in%20Alachua%2C%20Florida%2C%20the,agents%20and%20emerging%20infectious%20 diseases>.

<sup>32</sup> SAM.gov, “A—Medical Countermeasure Manufacturing Advanced Development Manufacturing (ADM) Capability,” Presolicitation Notice ID W911QY11R0023, August 9, 2011, at <https://sam.gov/opp/6d98c844d9d76510d7cf6bfdeffcf33e/view>.

<sup>33</sup> U.S. Government Accountability Office (GAO), *Biological Defense: Additional information that Congress may find useful as it considered DOD's advanced development and manufacturing capability*, GAO-17-701, July 2017, p. 7, at <https://www.gao.gov/assets/gao-17-701.pdf>; and White House, Memorandum for the Secretary of Defense, “Medical Countermeasures against Biological and Other Public Health Threats,” December 29, 2010.

<sup>34</sup> DOD, “Contracts for March 21, 2013,” accessed April 8, 2024, at <https://web.archive.org/web/20130408205027/http://www.defense.gov/contracts/contract.aspx?contractid=5002>; Kelly Burkhalter, “Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience,” *JPEO-CBRND News*, December 4, 2023, at <https://www.dvidshub.net/news/459375/enduring-capability-jpeo-cbrnd-evolves-public-private-partnership-with-national-resilience>; and Anthony Clark, “U.S. Department of Defense Expands Medical Countermeasure Capabilities,” *JPEO-CBRND News*, December 20, 2016, at <https://www.jpeocbrnd.osd.mil/Media/News/Article/2597346/us-department-of-defense-expands-medical-countermeasure-capabilities/>. In 2017, Nanotherapeutics, Inc. was renamed to Ology Bioservices, Inc. In 2021, National Resilience, Inc. acquired Ology Bioservices.

<sup>35</sup> Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), “Medical Countermeasures Advanced Development and Manufacturing (ADM),” accessed April 8, 2024, at [https://www.jpeocbrnd.osd.mil/Portals/90/fact-sheet\\_adm.pdf](https://www.jpeocbrnd.osd.mil/Portals/90/fact-sheet_adm.pdf); JPEO-CBRND, “JPEO-CBRND Capabilities Catalog,” 2023, at [https://www.jpeocbrnd.osd.mil/Portals/90/Documents/JPEO-CBRND\\_Capabilities%20Catalog\\_20%20April%202023\\_Final.pdf](https://www.jpeocbrnd.osd.mil/Portals/90/Documents/JPEO-CBRND_Capabilities%20Catalog_20%20April%202023_Final.pdf); and Hannah Feldman, Chris Earhart, and Traci Pals, “Toxic at Best,” *JPEO-CBRND News*, January 22, 2019, at <https://www.jpeocbrnd.osd.mil/Media/News/Article/2593990/toxic-at-best/>.







# NANOTHERAPEUTICS ADVANCED DEVELOPMENT AND MANUFACTURING (THE NANO-ADM CENTER)

## Summary

Nanotherapeutics Advanced Development and Manufacturing is a privately-held emerging biopharmaceutical company with expertise in pre-clinical and clinical development, formulation optimization, and cGMP manufacturing of vaccines, biopharmaceutical products, and medical devices. The facility provides research and quality control laboratories, BSL-3 bio-containment laboratories and production areas, pilot plant, warehouse, administration offices, and a conference center. Each function is zoned to allow for individual expansion. Production area utilities are fed from an interstitial space. Moses Engineering worked hand in hand with The Whiting-Turner Contracting Company who was the builder and RS&H who was chosen as the Architect to design this Advanced Development and Manufacturing Center based upon a depth of expertise in Health and Science facility design and the ability to work as a team member in this public-private partnership. The commissioning (Cx) process is an integrated set of activities intended to ensure that the project meets both the design goals and the owner's operational requirements. An owner's goals and objectives is what drives the project team. The value of Cx lies in its power to verify that those goals and objectives are met and that building systems perform as intended. The Cx Plan is a document that outlines the organization, schedule, allocation of resources, and documentation requirements of the Commissioning Process.

---

### Owner

Ology Bioservices

### Project Size

163,000 SF

### Services

Design



Department of Defense  
Fiscal Year (FY) 2020 Budget Estimates

March 2019



**Chemical and Biological Defense Program**

*Defense-Wide Justification Book Volume 4 of 5*

**Research, Development, Test & Evaluation, Defense-Wide**

[https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2020/budget\\_justification/pdfs/03\\_RDT\\_and\\_E/RDTE\\_Vol4\\_CBDP\\_RDTE\\_PB20\\_Justification\\_Book.pdf](https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2020/budget_justification/pdfs/03_RDT_and_E/RDTE_Vol4_CBDP_RDTE_PB20_Justification_Book.pdf)

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program		Date: March 2019
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (Number/Name)
0400 / 4	PE 0603884BP / CHEMICAL/BIOLOGICAL DEFENSE (ACD&P)	MB4 / MEDICAL BIOLOGICAL DEFENSE (ACD&P)
<p>emerging threats. Once established, future programs will be able to leverage these platforms for the development of future medical countermeasures. It is anticipated that these efforts will leverage the Other Transactions Authority (OTA) through the medical OTA consortium.</p> <p><b>ADVANCED DEVELOPMENT &amp; MANUFACTURING (ADM)</b></p> <p>A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) ADM Facility to rapidly develop, approve (through FDA approval), and manufacture MCMs. The contract was structured to be executed in two (2) phases:</p> <p>Phase 1-Establish, commission and validate (facility(ies)/ equipment) for two (2) advanced development and manufacturing suites that use agile, flexible (single use, disposable), modular and multi-product technologies for MCM advanced development and manufacturing. Both suites must meet Biological Safety Level-3 (BSL-3) standards. Phase 1 was completed on 31 March 2017.</p> <p>Phase 2-Support and maintain that capability in a state of readiness to support MCM development (under the animal rule as applicable) and manufacturing and assist in training personnel in its use. This includes transition and integration of new technologies, from Pre-Investigational New Drug Application phase with readiness to support simultaneous operations, through FDA licensure. The first option is scheduled for completion in 2QFY19, preceded by a second, 2-year option.</p> <p><b>BSL4 GOOD LABORATORY PRACTICES TEST &amp; EVALUATION (BSL4 GLP T&amp;E)</b></p> <p>The Medical Countermeasure Systems (MCM) BSL-4 T&amp;E capability continues to utilize and maintain a testing capability at the existing and planned new USAMRIID facilities. MCM BSL-4 T&amp;E costs support testing of MCMs against threats that require high-level containment using non-human primates. The period of FY18 and beyond will continue to support the BSL-4 T&amp;E capability.</p> <p><b>COUNTERMEASURES FOR DRUG RESISTANT BACTERIA (CMDR-B)</b></p> <p>The CMDR-B program develops MCMs for Service members for protection against MDR bacteria, including Biological Warfare Agents (BWAs) and organisms that are genetically modified to be MDR and resulting bio-toxins. The resulting product(s) will be US Food and Drug Administration (FDA)-approved to prevent or minimize effects of MDR bacterial exposures. The candidate is a transitional product from S&amp;T that showed efficacy against plague, anthrax, and other BW agents. The regulatory approach of the program is to pursue development of products to FDA approval under the Animal Rule. The program will conduct non-human primate studies to initial efficacy. The performer will submit Supplemental New Drug Application for the therapeutic during the EMD Phase. In FY18 PK study on non-human primates was completed for the plague indication. MS B for the program is planned for 4QFY20.</p> <p><b>NEXT GENERATION DIAGNOSTICS SYSTEM (NGDS)</b></p> <p>The NGDS Increment 1 program was a MS A to MS C - acquisition strategy, with MS C approval granted in Dec 2016 for limited production and fielding. NGDS 1 is replacing the legacy Joint Biological Agent Identification and Diagnostic System (JBAIDS) beginning in FY17. NGDS 1 Full Rate Production was approved in Aug 2018.</p>		

Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program		Date: March 2019
Appropriation/Budget Activity 0400 / 5	R-1 Program Element (Number/Name) PE 0604384BP / CHEMICAL/BIOLOGICAL DEFENSE (EMD)	Project (Number/Name) MB5 / MEDICAL BIOLOGICAL DEFENSE (EMD)

JOINT MOBILE EMERGING DISEASE INTERVENTION CLINICAL CAPABILITY (JMEDICC)

The Joint Mobile Emerging Disease Intervention Clinical Capability (JMEDICC) is a collaboration between United States and Ugandan research and outbreak response entities. It currently is a joint effort with The United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and The Naval Medical Research Center (NMRC) to enable clinical trials for filovirus (i.e., Ebola and Marburg) therapeutics during an outbreak. Prior to Fiscal Year 2020, this effort was funded under the Antiviral Therapeutics (AV TX) Program. The JMEDICC effort is currently focused on filovirus, but is an adaptable capability that can incorporate multiple different medical countermeasures (MCM) in parallel and accommodate multiple site activities. This will maximize JMEDICC's current response capability and infrastructure by expanding as the endemic situation warrants. A cost sharing plan is currently being explored with other government and nongovernment agencies to determine interest and relevance levels. Antiviral Therapeutics program funded JMEDICC effort through FY19.

ADVANCED DEVELOPMENT & MANUFACTURING (ADM)

A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) ADM Facility to rapidly develop, approve (through FDA approval), and manufacture MCMs. The contract was structured to be executed in two (2) phases:

Phase 1-Establish, commission and validate (facility(ies)/ equipment) for two (2) advanced development and manufacturing suites that use agile, flexible (single use, disposable), modular and multi-product technologies for MCM advanced development and manufacturing. Both suites must meet Biological Safety Level-3 (BSL-3) standards. Phase 1 was completed on 31 March 2017.

Phase 2-Support and maintain that capability in a state of readiness to support MCM development (under the animal rule as applicable) and manufacturing and assist in training personnel in its use. This includes transition and integration of new technologies, from Pre-Investigational New Drug Application phase with readiness to support simultaneous operations, through FDA licensure. The first option is scheduled for completion in 2QFY19, proceeded by a second, 2-year option.

COUNTERMEASURES FOR DRUG RESISTANT BACTERIA (CMDR-B)

The CMDR-B program develops MCMs for Service members for protection against MDR bacteria, including Biological Warfare Agents (BWAs) and organisms that are genetically modified to be MDR and resulting bio-toxins. The resulting product(s) will be US Food and Drug Administration (FDA)-approved to prevent or minimize effects of MDR bacterial exposures. The candidate is a transitional product from S&T that showed efficacy against plague, anthrax, and other BW agents. The regulatory approach of the program is to pursue development of products to FDA approval under the Animal Rule. The program will conduct non-human primate studies to initial efficacy. The performer will submit Supplemental New Drug Application for the therapeutic during the EMD Phase. In FY18 PK study on non-human primates was completed for the plague indication. MS B for the program is planned for 4QFY20.

NEXT GENERATION DIAGNOSTICS SYSTEM (NGDS)

Department of Defense  
Fiscal Year (FY) 2020 Budget Estimates

March 2019



Chemical and Biological Defense Program

Defense-Wide Justification Book Volume 4 of 5

Research, Development, Test & Evaluation, Defense-Wide

[https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2020/budget\\_justification/pdfs/O3\\_RDT\\_and\\_E/RDTE\\_Vol4\\_CBDP\\_RDTE\\_PB20\\_Justification\\_Book.pdf](https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2020/budget_justification/pdfs/O3_RDT_and_E/RDTE_Vol4_CBDP_RDTE_PB20_Justification_Book.pdf)



Department of Defense  
Fiscal Year (FY) 2021 Budget Estimates

February 2020



Chemical and Biological Defense Program

# February 2020

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2021 Chemical and Biological Defense Program										Date: February 2020	
Appropriation/Budget Activity 0400 / 4			R-1 Program Element (Number/Name) PE 0603884BP / CHEMICAL/BIOLOGICAL DEFENSE (ACD&P)				Project (Number/Name) MB4 / Medical Biological Defense (ACD&P)				
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
• JX0210: DEFENSE BIOLOGICAL PRODUCTS ASSURANCE PROGRAM (DBPAP)	0.975	2.961	2.845	-	2.845	2.760	2.736	2.736	2.736	Continuing	Continuing
Remarks											
D. Acquisition Strategy											
BSL4 GOOD LABORATORY PRACTICES TEST & EVALUATION (BSL4 GLP T&E)											
The Medical Countermeasure Systems (MCM) BSL-4 T&E capability continues to utilize and maintain a testing capability at the existing and planned new USAMRIID facilities. MCM BSL-4 T&E costs support testing of MCMs against threats that require high-level containment using non-human primates. The period of FY18 and beyond will continue to support the BSL-4 T&E capability. In FY21 and beyond, the Defense-Wide Review reduced this program for higher priorities.											
CHEM BIO INCIDENT PREPAREDNESS AND RESPONSE - BIOSAFETY LEVEL 4 RESEARCH INSTITUTE OF INFECTIOUS DISEASES (CBIPR-BSL4 RIID)											
The Medical Countermeasure Systems (MCM) BSL-4 T&E capability continues to utilize and maintain a testing capability at the existing and planned new USAMRIID facilities. MCM BSL-4 T&E costs support testing of MCMs against threats that require high-level containment using non-human primates. The period of FY18 and beyond will continue to support the BSL-4 T&E capability.											
CHEM BIO INCIDENT PREPAREDNESS AND RESPONSE - ADM											
A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) ADM Facility to rapidly develop, approve (through FDA approval), and manufacture MCMs. The contract was structured to be executed in two (2) phases:											
Phase 1-Establish, commission and validate (facility(ies)/ equipment) for two (2) advanced development and manufacturing suites that use agile, flexible (single use, disposable), modular and multi-product technologies for MCM advanced development and manufacturing. Both suites must meet Biological Safety Level-3 (BSL-3) standards. Phase 1 was completed on 31 March 2017.											
Phase 2-Support and maintain that capability in a state of readiness to support MCM development (under the animal rule as applicable) and manufacturing and assist in training personnel in its use. This includes transition and integration of new technologies, from Pre-Investigational New Drug Application phase with readiness to support simultaneous operations, through FDA licensure. The first sustainment option (POP 2 years) was completed in 2QFY19; the subsequent sustainment option began thereafter and is scheduled for completion in 4QFY20, but can be extended until 2QFY21 if needed.											

UNCLASSIFIED

February 2020



Chemical and Biological Defense Program

[https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2021/budget\\_justification/pdfs/03\\_RDT\\_and\\_E/RDTE\\_Vol4\\_CBDP\\_RDTE\\_PB21\\_Justification\\_Book.pdf](https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2021/budget_justification/pdfs/03_RDT_and_E/RDTE_Vol4_CBDP_RDTE_PB21_Justification_Book.pdf)

# February 2020

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2021 Chemical and Biological Defense Program		Date: February 2020
Appropriation/Budget Activity 0400 / 5	R-1 Program Element (Number/Name) PE 0604384BP / CHEMICAL/BIOLOGICAL DEFENSE (EMD)	Project (Number/Name) MB5 / Medical Biological Defense (SDD)
<p>CHEM BIO INCIDENT PREPAREDNESS AND RESPONSE - ADM</p> <p>A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) ADM Facility to rapidly develop, approve (through FDA approval), and manufacture MCMs. The contract was structured to be executed in two (2) phases:</p> <p>Phase 1-Establish, commission and validate (facility(ies)/ equipment) for two (2) advanced development and manufacturing suites that use agile, flexible (single use, disposable), modular and multi-product technologies for MCM advanced development and manufacturing. Both suites must meet Biological Safety Level-3 (BSL-3) standards. Phase 1 was completed on 31 March 2017.</p> <p>Phase 2-Support and maintain that capability in a state of readiness to support MCM development (under the animal rule as applicable) and manufacturing and assist in training personnel in its use. This includes transition and integration of new technologies, from Pre-Investigational New Drug Application phase with readiness to support simultaneous operations, through FDA licensure. The first sustainment option (POP 2 years) was completed in 2QFY19; the subsequent sustainment option began thereafter and is scheduled for completion in 4QFY20, but can be extended until 2QFY21 if needed.</p> <p>COUNTERMEASURES FOR DRUG RESISTANT BACTERIA (CMDR-B)</p> <p>The CMDR-B program develops MCMs for Service members for protection against MDR bacteria, including Biological Warfare Agents (BWAs) and organisms that are genetically modified to be MDR and resulting bio-toxins. The resulting product(s) will be US Food and Drug Administration (FDA)-approved to prevent or minimize effects of MDR bacterial exposures. The candidate is a transitional product from S&amp;T that showed efficacy against plague, anthrax, and other BW agents. The regulatory approach of the program is to pursue development of products to FDA approval under the Animal Rule. The program will conduct non-human primate studies to confirm efficacy. The performer will develop and submit an IFC package to FDA for emergency use to support the warfighter preparedness against MDR. The performer will submit Supplemental New Drug Application for the therapeutic during the EMD Phase. In FY18 PK study on non-human primates was completed for the plague indication and results were analyzed against threat indication. Continued coordination with FDA for supplemental indication of anthrax based on threat level to the warfighter. In FY21 and beyond, the Defense-Wide Review reduced this program for higher priorities.</p> <p>MCM PLATFORM TECHNOLOGIES (MCMPT)</p> <p>The goal of the MCMPT is to rapidly counter a broad-spectrum of threat agents using standardized discovery, design, manufacturing, and testing processes to reduce the MCM development risks. Efforts will focus on establishing advanced platform technologies within the DoD's Advanced Development Manufacturing (ADM) facility and evaluating that capability through nonclinical and clinical testing. A subset of these technologies will be adapted to deliver a rapid response capability to novel and emerging threats. Once established, future programs will be able to leverage these platforms for the development of future medical countermeasures. It is anticipated that these efforts will leverage the Other Transactions Authority (OTA) through the medical OTA consortium.</p> <p>NEXT GENERATION DIAGNOSTICS SYSTEM (NGDS)</p>		



May 2021

UNCLASSIFIED

UNCLASSIFIED

Department of Defense  
Fiscal Year (FY) 2022 Budget Estimates

May 2021



Chemical and Biological Defense Program

Defense-Wide Justification Book Volume 4 of 5

Research, Development, Test & Evaluation, Defense-Wide

Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (Number/Name)
0400 / 5	PE 0604384BP / CHEMICAL/BIOLOGICAL DEFENSE (EMD)	MB5 / Medical Biological Defense (SDD)
<p>The COVID TX program will conduct Phase 2 clinical trials in FY20 and FY21 to test the efficacy of the Leukine (sargramostim, rhu-GM-CSF) in COVID-19 patients with acute hypoxemia to inform a request for Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA). Qualification of a second manufacturing line for Drug Product Agreement awarded to performer for clinical trials, submission of EUA, and manufacturing expansion.</p> <p>ANTI-VIRAL THERAPEUTICS (AV TX)</p> <p>The Anti-viral Therapeutics (AVTX) program acquisition strategy supports the development of therapeutics through the Engineering, Manufacturing and Development (EMD) phase against the Ebola (Zaire), Marburg and Sudan bio warfare threats. The initial therapeutic candidate is now for a treatment against the Marburg virus in lieu of Ebola Zaire based on the current gap in defense to the warfighter. The overall regulatory approach of the program remains to pursue development of products to Food and Drug Administration (FDA) approval under the Animal Rule that was approved as the path, by the FDA in 1QFY19. The program completed a dose ranging study for the Ebola Zaire indication and initiated a Natural History Study for Marburg that is part of the holistic FDA regulatory approach for a final indication of a broad spectrum antiviral pan filo drug product. A natural history study for Marburg and Sudan and 3 pivotal animal studies per indication are required as part of the animal rule requirements for the FDA) approved plan. The acquisition strategy for Marburg and Sudan indications will have the performer submitting amended New Drug applications for the therapeutics during the EMD phase.</p> <p>BOTULINUM MONOCLONAL ANTIBODIES (BOT MAB)</p> <p>Initiated by the Medical Countermeasure Platform Technologies (MCMPT), the goal of Botulinum Monoclonal Antibodies (BOT MAB) advanced development effort is to counter exposure to BOT A &amp; B toxins. The program is leveraging the advanced platform technology developed within the DoD's Advanced Development Manufacturing (ADM) facility that was initiated by the Medical Countermeasure Platform Technologies (MCMPT). The BOT MAB will be a monoclonal antibody cocktail that protects the warfighter against exposure to BOT A&amp;B serotypes.</p> <p>COUNTERING EMERGING THREATS RAPID ACQUISITION AND INVESTIGATION OF DRUGS FOR REPURPOSING (CET RAIDR)</p> <p>The Countering Emerging Threats - Rapid Acquisition and Investigation of Drugs for Repurposing (CET RAIDR) program will leverage lessons learned from the COVID-19 response to conduct nonclinical studies and Phase 2 and 3 trials in support of requesting pre-Emergency Use Authorizations (pre-EUA). Repurposing reports will be issued to Combatant Commands to inform clinical practitioners, and Food and Drug Administration (FDA) approvals for those efforts initiated under the Coronavirus Disease Repurposed Therapeutics (COVID TX) program, as well as products that transition from Science and Technology (S&amp;T) efforts for new and emerging threats.</p> <p>CHEM BIO INCIDENT PREPAREDNESS AND RESPONSE - ADM</p> <p>A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) Advanced Development and Manufacturing (ADM) capability that can rapidly develop and manufacture MCMs from early stage development up through FDA licensure. The establishment of this capability consisted of designing, commissioning, and validating a biopharmaceutical facility (both its infrastructure and equipment) that is equipped with two (2)</p>		

DEFENSE

Chemical and Biological Defense Program

PE 0604384BP: CHEMICAL/BIOLOGICAL DEFENSE (EMD)

Chemical and Biological Defense Program

UNCLASSIFIED

Page 110 of 151

R-1 Line #129

Volume 4 - 292

[https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2022/budget\\_justification/pdfs/03\\_RDT\\_and\\_E/RDTE\\_Vol4\\_CBDP\\_RDTE\\_PB22\\_Justification\\_Book.pdf](https://comptroller.defense.gov/Portals/45/Documents/defbudget/fy2022/budget_justification/pdfs/03_RDT_and_E/RDTE_Vol4_CBDP_RDTE_PB22_Justification_Book.pdf)

Defense-Wide Justification Book Volume 4 of 5

May 2021

UNCLASSIFIED

Department of Defense  
Fiscal Year (FY) 2022 Budget Estimates

May 2021



**Chemical and Biological Defense Program**

*Defense-Wide Justification Book Volume 4 of 5*

***Research, Development, Test & Evaluation, Defense-Wide***



Exhibit R-2A, RDT&E Project Justification: PB 2022 Chemical and Biological Defense Program		Date: May 2021
Appropriation/Budget Activity 0400 / 4	R-1 Program Element (Number/Name) PE 0603884BP / CHEMICAL/BIOLOGICAL DEFENSE (ACD&P)	Project (Number/Name) MB4 / Medical Biological Defense (ACD&P)
<p>A contract was awarded to Ology Bioservices on 20 March 2013 (then Nanotherapeutics, Inc.) to establish a Department of Defense (DoD) Advanced Development and Manufacturing (ADM) capability that can rapidly develop and manufacture MCMs from early stage development up through FDA licensure. The establishment of this capability consisted of designing, commissioning, and validating a biopharmaceutical facility (both its infrastructure and equipment) that is equipped with two (2) advanced development and manufacturing suites, which utilize flexible, agile, single-use (disposable), modular, and multi-product technologies that comply with GMPs and can operate at Biological Safety Level-3 (BSL-3). The capability was established on 31 March 2017.</p> <p>Since its establishment, the DoD ADM has been sustained in a state of operational readiness so that it can continue to be an enduring domestic MCM manufacturing capability that provides the DoD with priority access. The original sustainment strategy consisted of directly funding all costs/activities (i.e. calibration, maintenance, etc.) via sustainment options on the original contract. The CBIPR funds were designated to support this critical DoD infrastructure. The CBIPR-ADM funding line supports the infrastructure by funding new capability-building efforts (such as manufacturing platforms using FDA known technologies) that will enable new additional MCM product development. This strategy will result in the self-sustainability of the DoD ADM by spreading the sustainment costs equally across all projects (including commercial clients), which mimics the standard practice across the contract development and manufacturing organization (CDMO) industry.</p> <p><b>MCM PLATFORM TECHNOLOGIES (MCMPT)</b></p> <p>The goal of the MCMPT is to rapidly counter a broad-spectrum of threat agents using standardized discovery, design, manufacturing, and testing processes to reduce the MCM development risks. Efforts will focus on establishing advanced platform technologies within the DoD's Advanced Development Manufacturing (ADM) facility and evaluating that capability through nonclinical and clinical testing. A subset of these technologies will be adapted to deliver a rapid response capability to novel and emerging threats. Once established, future programs will be able to leverage these platforms for the development of future medical countermeasures. It is anticipated that these efforts will leverage the Other Transactions Authority (OTA) through the medical OTA consortium.</p> <p><b>NEXT GENERATION DIAGNOSTICS SYSTEM (NGDS)</b></p> <p>The NGDS 1 program was a MS A to MS C - acquisition strategy, with MS C approval granted in Dec 2016. NGDS 1 replaces the legacy Joint Biological Agent Identification and Diagnostic System (JBAIDS). NGDS 1 Full Rate Production was approved in Aug 2018.</p> <p>NGDS 2 will employ a family of systems approach to bridge identified capability gaps for man-portable diagnostics, immunoassay diagnostics, and chemical diagnostics systems. NGDS 2 continued the technology maturation and risk reduction of a man-portable diagnostic capability in FY18 and transitioned to engineering and manufacturing development phase in FY19. NGDS 2 initiated prototyping of a chemical diagnostic capability in FY18. Separate decisions will be utilized to proceed with further development and production for each capability, based on individual determinations of technology maturity to meet user requirements. Development efforts are cost-plus awards using Other Transactions Authority (OTA) agreements to take advantage of nontraditional Defense contractor offerings. NGDS 2 will transition into NGDS 2 CHEMDx and NGDS 2 MPDS starting in FY21.</p> <p><b>NEXT GEN DIAG 2 CHEMICAL DIAGNOSTICS (NGDS 2 CHEMDX)</b></p>		

**e Program**



# Strategic Alliance Formed To Advance National Biodefense Programs

PharmAthene and Nanotherapeutics, a privately-held biopharmaceutical company, have announced that they have formed a Strategic Alliance to advance the development of certain medical countermeasures for the U.S. biodefense market. Under the Alliance Agreement, each company will contribute...

By The Associated Press

Sep 8, 2014

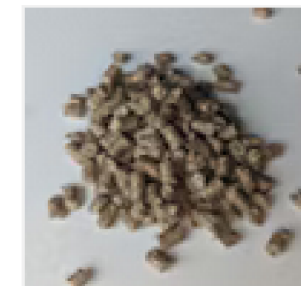
PharmAthene, Inc. and Nanotherapeutics, Inc., a privately-held biopharmaceutical company, have announced that they have formed a Strategic Alliance to advance the development of certain medical countermeasures for the U.S. biodefense market. Under the Alliance Agreement, each company will contribute its specific expertise and resources with the objective of advancing biodefense products to be agreed to under individual product plans.

---

## Latest in Operations

**Chemovator Invests in Detroit-Based Startup, Rethinking Plastics**

May 2, 2024



<https://www.manufacturing.net/operations/news/13095313/strategic-alliance-formed-to-advance-national-biodefense-programs>







# ADEPT : PROTECT

## THE DARPA SOLUTION

In 2012 with the ADEPT:PROTECT program\*, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses

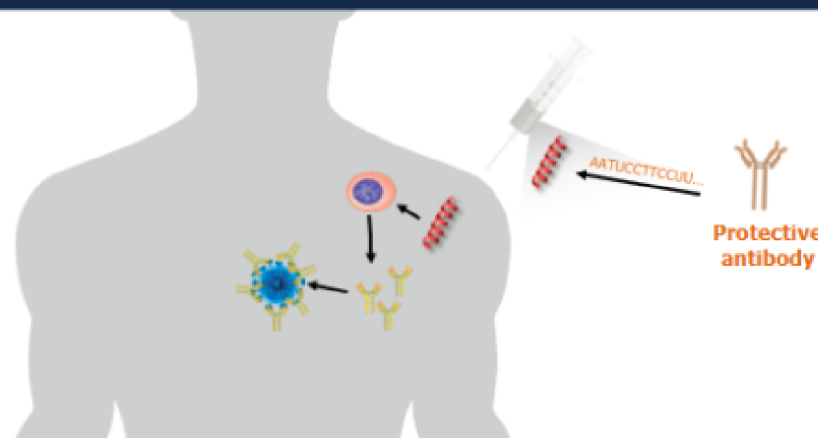
## THE IMPACT

DARPA's investments in this space led directly, with the biotechnology firm Moderna as a contracted performer on the program, to a first-ever human clinical trial with an RNA vaccine in 2019.

# DARPA P3

DARPA pioneered the use of the body as a bioreactor to produce prophylactic antibodies to protect against biothreats

**Gene-encoded antibodies**  
for near-immediate, temporary  
protection  
(ADEPT-PROTECT)



Proof-of-concept in animal models (6.1)

2013-2016

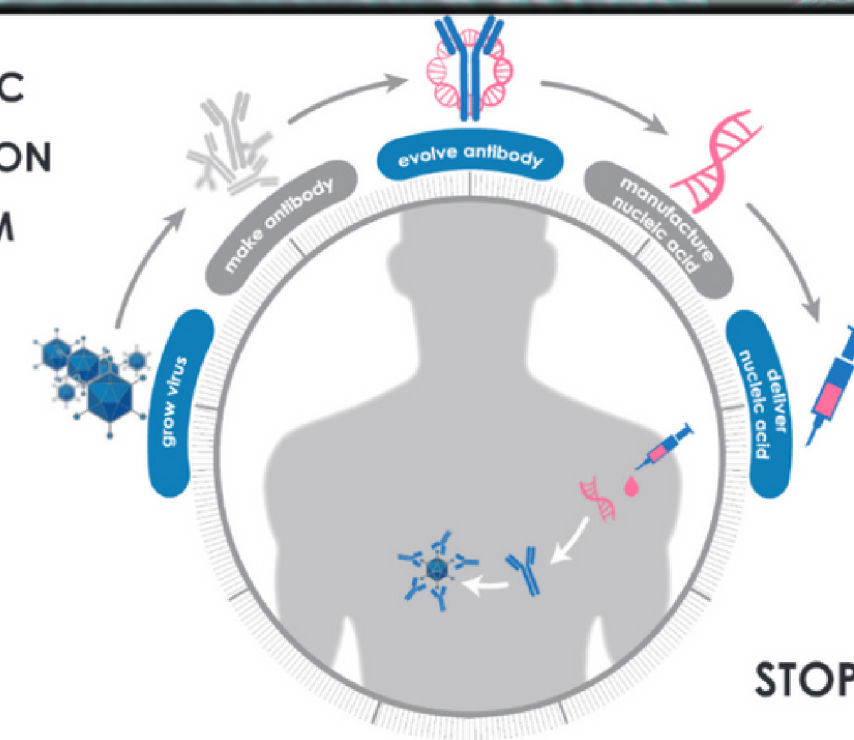
Pre-clinical studies & GMP manufacture  
(6.1 to 6.2)

2017-2018

Gene-encoded antibody safety and  
expression study in humans (performer  
funded)

2018-2020

## PANDEMIC PREVENTION PLATFORM (P3)



**60 DAYS TO  
STOP A PANDEMIC**

A follow-on effort to the ADEPT program, known as the Pandemic Prevention Platform program, aims to take pandemics off of the list of humanity's angsts with a range of technologies and practices marked by early detection of an outbreak and, within 60 days, development and widescale deployment of protective countermeasures.



# ADEPT : PROTECT

## THE NEED AND OPPORTUNITY

A primary objective of DARPA's Biological Technologies Office (BTO) is to better ensure the health, and thereby the force readiness, of the country's military service community. The COVID-19 pandemic, which rapidly spread worldwide from an initial outbreak in China at the end of 2019, highlights one of the most perilous vulnerabilities to deployed military personnel and civilians: lack of protection and medical countermeasures (MCMs) against endemic and emerging biothreats. The Zika outbreak in 2015-2016, the more recent Ebola outbreak in the Democratic Republic of Congo, and mosquito-borne viruses such as Chikungunya and Dengue are among these threats.

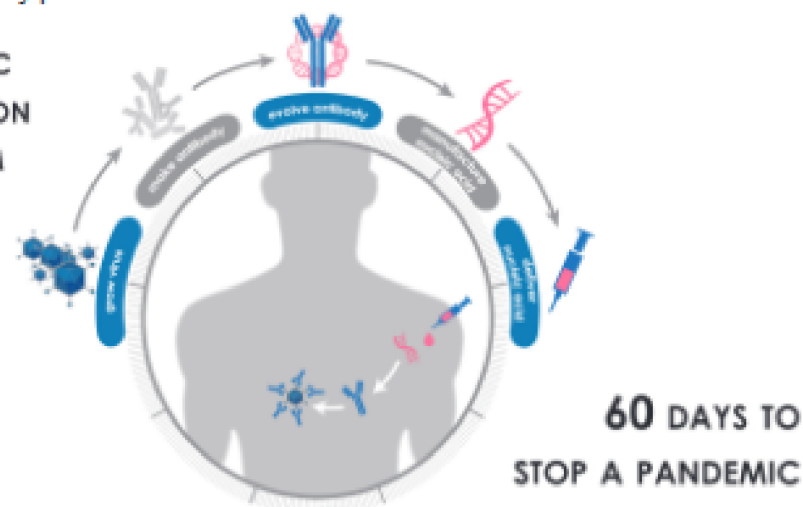
Vaccines are the traditional mainstay of long-term infection prevention, while antibody approaches have at times been used to treat active infections. In one antibody-based approach that is being applied on a small scale in the current pandemic, blood serum with presumably protective antibodies

obtained from those who have recovered from an infection is infused into patients. In more recent decades, monoclonal antibodies manufactured in cultured immune-system cells have been used to treat certain cancers and immune disorders. However, these treatments have suffered from shortcomings – including slow development, expensive manufacture, and dependence on continuous cold storage – that have prevented widespread use by the military.

## THE DARPA SOLUTION

In 2012 with the ADEPT:PROTECT program\*, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses like the one (SARS-CoV-2) that causes COVID-19, are delivered directly to a recipient's body. There, the instructions carried in the DNA or RNA elicit the body's own cells to manufacture the antigenic viral protein, which, in turn, elicits an immune response to the virus.

## PANDEMIC PREVENTION PLATFORM (P3)



A follow-on effort to the ADEPT program, known as the Pandemic Prevention Platform program, aims to take pandemics off of the list of humanity's angsts with a range of technologies and practices marked by early detection of an outbreak and, within 60 days, development and widescale deployment of protective countermeasures.

Gene-based vaccines have shown great promise as a means to provide safe, reproducible, long-term immune protection. For vaccines to work, however, they often require more than one dose and it often takes weeks to months before a recipient's immune system builds up sufficient protection against the vaccine's viral target. With these biomedical realities come threats to warfighters if they deploy to pathogen-rife regions before having established relevant immunity and threats to military missions due to delayed deployment of personnel until they achieve immune protection.

For a vaccine to confer immunity, it must lead to the production within a recipient of highly potent antibodies that can neutralize the pathogen. DARPA initiated the ADEPT:PROTECT program (most often referred to more simply as ADEPT) with the intention of bushwhacking a novel pathway to near-immediate protection against pathogens for which vaccines are not yet available and to confer interim-term protection during the development of a vaccine, which can take years.

## THE IMPACT

DARPA's investments in this space led directly, with the biotechnology firm Moderna as a contracted performer on the program, to a first-ever human clinical trial with an RNA vaccine in 2019.

Earlier proof-of-concept experiments funded under ADEPT primarily with 6.1 funding (for basic research) demonstrated that delivery of antibody-making instructions – by way of messenger ribonucleic acid (mRNA), deoxyribonucleic acid (DNA), or another genetic-information-carrying tactic that relies on small viruses known as adenovirus-associated viruses (AAVs)

DARPA pioneered the use of the body as a bioreactor to produce prophylactic antibodies to protect against biothreats

Gene-encoded antibodies for near-immediate, temporary protection (ADEPT-PROTECT)

Proof-of-concept in animal models (6.1)  
2013-2016

Pre-clinical studies & GMP manufacturing (6.1 to 6.2)  
2017-2018

— led to the production of antibodies that conferred protection in test animals exposed to the mosquito-borne Chikungunya (ChikV) virus.

In a more applied phase of technology development, Moderna was converted to 6.2 funding (applied research) to begin pre-clinical studies in non-human primates with an RNA-encoded antibody against ChikV and to produce the countermeasure using Good Manufacturing Practices (GMP), which regulatory agencies such as the Food and Drug Administration often require.

Moderna subsequently used company funding to conduct a Phase I clinical trial with 22 healthy volunteers using an mRNA-encoded ChikV antibody. This marked the first safety demonstration of an RNA-based medical countermeasure. Moderna reported these promising results of its clinical study in 2019. The trial demonstrated platform safety as well as the ability to generate protective levels of functional antibody in humans. In response to COVID-19, Moderna in March 2020 initiated human trials of gene-encoded antibodies that target SARS-CoV-2.

Research by Moderna and other ADEPT performers has provided proof-of-concept results that simultaneously delivering gene-encoded antibody treatment and vaccine confers the recipient with immediate immune

based on a monoclonal antibody referred to as mAb-114, which was previously discovered by scientists at NIAID's Vaccine Research Center. This therapeutic antibody was authorized for emergency use (EUA) in the 2017

based on a monoclonal antibody referred to as mAb-114, which was previously discovered by scientists at NIAID's Vaccine Research Center. This therapeutic antibody was authorized for emergency use (EUA) in the 2017 Ebola outbreak in the Democratic Republic of Congo, where it conferred significant survival benefits over other EUA-sanctioned Ebola therapeutics. To enable continued availability of mAb-114, DARPA and JPEO-CBRND in 2018 co-funded the manufacture of additional doses at Ology Biosciences through its DoD-funded Advanced Development and Manufacturing (ADM) facility.

and Contagious Threats (ADEPT: PROTECT)













































































































# Board of Directors

# [RESILIENCE



Robert Nelsen  
Chairman and Founder, ARCH



Patrick Y. Yang, PhD  
Vice Chairman, Former EVP Juno,  
Roche, Genentech



Drew Gelling  
Co-founder & President, BMC,  
Co-founder Affinity



Rahul Singhal, ScD  
Co-founder, CEO



Joe Lonsdale



Frances Arnold, PhD  
Nobel Prize Laureate, CalTech  
Professor



George Barrett  
Former Chairman & CEO,  
Cardinal Health



Mitchell E. Daniels, Jr.  
President, Purdue University,  
Former Governor of Indiana



Chris Darby  
CEO, In-Q-Tel

ALL HIGHLIGHTED  
INDIVIDUALS HAVE TIES TO  
THE INTELLIGENCE  
COMMUNITY



# Backed by investors with an unmatched record of success



**GV = GOOGLE VENTURES**  
**FORMER BILL & MELINDA GATES FOUNDATION**  
**CEO AND CURRENT BOARD MEMBER OF:**  
**RESILIENCE AND PFIZER,**

**G/**  
Advisor

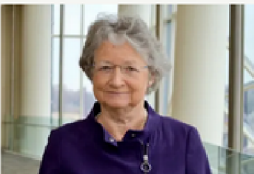
ABOUT  
Advisor


TEAM  
Advisor

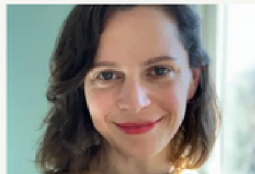
NEWS  
Advisor


PORTFOLIO  
Advisor


SOCIAL  
Advisor

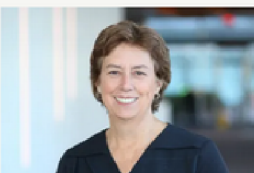
  
Kathy High  
Advisor


  
Kunle Olukotun  
Advisor


  
Margaret McKenna  
Advisor

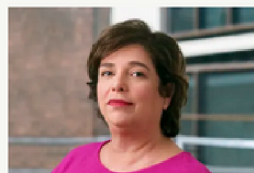
  
Melissa McLaughlin  
Advisor


  
Nadia Bowlinson  
Advisor

  
Nancy Thornberry  
Advisor

  
Pooja Chandrashekar

  
Richard Scheller  
Advisor

  
Rosana Kapeller  
Advisor

  
Sue Desmond-Hellmann

Launched as Google Ventures in 2009, GV originated as an independent venture capital firm for innovative founders. While today we're formally known as GV, our previous moniker (Google Ventures) is the root of our DNA. With Alphabet as our sole limited partner, we focus all our energy on meeting and supporting founders at the earliest stages of company-building. GV's operating partners work to support startups across design, equity, diversity & inclusion, talent, and engineering. GV also helps startups interface with Google, providing unique access to the world's best technology and talent.

GV operates on long time horizons and deals in decades — not rounds. At launch, we had a \$60 million capital commitment and a desire to partner with founders moving the world forward. Today, GV has over \$10 billion in assets under management, 400 active portfolio companies across North America and Europe, and notable investment outcomes including Uber, Nest, Slack, GitLab, Duo Security, Flatiron Health, Verve Therapeutics, and One Medical.

## SUSAN DESMOND - HELLMAN





[Freda Lewis-Hall, MD,](#)



[Scott Gottlieb, MD](#)



[Frances Arnold, PhD](#)

## Dr. Freda Lewis-Hall Joins Pfizer As Chief Medical Officer

Monday, May 04, 2009 - 06:46am



Prominent Physician, Researcher and Business Leader Will Direct Global Medical and Regulatory Strategy, Join Executive Leadership Team

([BUSINESS WIRE](#))--Pfizer Inc announced today that Freda Lewis-Hall, M.D., has been appointed as Chief Medical Officer and Senior Vice President, Pfizer Inc. Dr. Lewis-Hall will be the senior physician in the company, responsible for enterprise-wide medical, patient safety, regulatory affairs and quality assurance as well as outreach to doctors and other medical professionals. She joins Pfizer from Vertex Pharmaceuticals, where she was responsible for clinical and non-clinical development as well as both medical and regulatory.

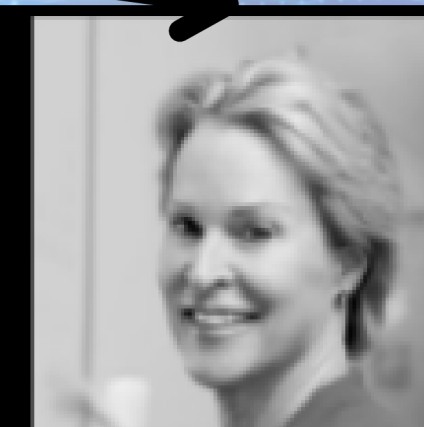


Scott Gottlieb, M.D.

Age: 51 years

Partner, New Enterprise Associates, Inc.'s Healthcare Investment Team and Resident Fellow of the American Enterprise Institute since 2019. Served as the 23rd Commissioner of the FDA from 2017 to 2019. Prior to serving as Commissioner of the FDA, Dr. Gottlieb held several roles in the public and private sectors, including serving as a Venture Partner to New Enterprise Associates, Inc. from 2007 to 2017.

Director of Illumina, Inc. Director of Aetion, Inc. a private healthcare data technology company, and Tempus, a private technology company. Board Member of National Resilience, Inc. Scientific Advisory Board Member of CellCarta. Member of the National Academy of Medicine and a contributor to the financial news network CNBC.



Frances Arnold, PhD

Nobel Prize Laureate, CalTech Professor

[RESILIENCE



# ROBERT NELSEN & LUCIANA BORIO



Bob Nelsen

Nelsen and Borio have worked closely in the past. He previously [told Endpoints News](#) that he spent last spring in his Seattle home, talking on the phone with Borio about her work running pandemic preparedness on the NSC, and fuming with her about the dire state of American manufacturing. Those talks helped lead to the launch of Nelsen's \$800 million biologics manufacturing startup Resilience.

Borio, who previously served as the FDA's acting chief scientist and as VP at that nonprofit investment firm In-Q-Tel, serves as a [senior fellow for global health](#) at

the Council on Foreign Relations for about the last year. Borio did not respond to a request for comment on whether she would keep that role at the CFR. She also serves as a member of CEPI's scientific advisory committee, where she provides Covid-related guidance and work on the public-private partnership's \$3.5 billion plan to reduce the threat of future pandemics and epidemics.

And she played a hand in President Biden's race to nominate an FDA commissioner, according to one former agency official.

[HTTPS://ARCHIVE.IS/VQK8G](https://archive.is/vqk8g)

**BOTH ON THE COUNCIL FOR  
FOREIGN RELATIONS**

**BOTH MEMBERS OF ARCH  
VENTURES**

**BOTH PLAYED KEY ROLES IN THE  
“CREATION OF RESILIENCE”**

During the saga around the first accelerated approval for Sarepta Therapeutics' DMD drug eteplirsen, Borio — then FDA's acting chief scientist — wrote to then-FDA commissioner Robert Califf with fears that current acting commissioner Jane Woodcock “chilled scientific debate within (the FDA Center for Drug Evaluation and Review) and reduced the level of participation by the review team during the final stages of the decision-making process.”

A former senior FDA official said it was this dispute that led Woodcock to push Borio out of the FDA entirely, after Borio circulated an internal memo concerning Woodcock's role with Sarepta. This former official also said he thinks Borio, who was vetted but ultimately not nominated to lead FDA, might have a hand in icing Woodcock's failure to land a nomination, too.





**OWS SPENT 1.5 BILLION ON MODERNA  
TO PROVIDE A C19 “VACCINE”**



**moderna**

**...BUT THE 10YR OLD COMPANY,  
THAT HAD NEVER PRODUCED  
ANY FDA APPROVED VACCINE  
BEFORE HAD TO OFFSHOOT THE  
PROJECT TO 2 COMPANIES**

**“NEW” US STARTUP,  
ESTABLISHED IN 2020**

**[RESILIENCE®]**



**Lonza**

**127 YEAR OLD SWISS COMPANY  
EST. 1897**

- Resilience was founded in 2020 by Drew Oetting, Patrick Yang, Sandesh Mahatme, and Rahul Singhvi. 1 2 3 4 5

Lonza Group AG was founded in 1897 in Gampel, Switzerland.



# “SINGHVI WAS ...AND AN OPERATING PARTNER AT FLAGSHIP PIONEERING, WHICH PLAYED A MAJOR ROLE IN THE CREATION OF MODERNA”

Prior to Resilience, Singhvi was CEO of Novavax and an operating partner at Flagship Pioneering, which played a major role in the creation and rise of Moderna.

Resilience was co-founded by Biotech venture capitalist Robert Nelsen, who is known for listening “to science’s earliest whispers, even when data are too early for just about anyone else.”

Nelsen was one of the earliest investors in Illumina, a California-based gene-sequencing hardware and software giant that is believed to currently dominate the field of genomics.

As mentioned in a previous Unlimited Hangout investigation, Illumina is closely tied to the Defense Advanced Research Projects Agency (DARPA) equivalent of the Wellcome Trust known as Wellcome Leap, which is also focused on “futuristic” and transhumanist “medicines.”

Nelsen is now chairman of National Resilience’s board, which is a “Who’s Who” of big players from the U.S. National Security State, Big Pharma and Pharma-related “philanthropy.”

[HTTPS://CHILDRENSHEALTHDEFENSE.ORG/DEFENDER/CIA-LINKED-MRNA-MODERNA-OMICRON-COVID-BOOSTER-SHOT/](https://childrenshealthdefense.org/defender/cia-linked-mrna-moderna-omicron-covid-booster-shot/)

CHILDREN’S HEALTH DEFENSE ET.  
WHITNEY WEBB



# LUCIANA BORIO

# GOTTLIEB

## Expert Bio

Luciana Borio is a senior fellow for global health at the Council on Foreign Relations (CFR). She also is a venture partner at Arch, a venture capital firm that provides seed/early-stage venture capital for technology firms in information technology, life sciences, and physical sciences. Dr. Borio specializes in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies.



Scott Gottlieb, MD

@ScottGottliebMD · Follow



Big congratulations to [@lborio](#) and to [@rtnarch](#) and the team at Arch Ventures. Dr. Borio is a great colleague and brings a deep record of skill and accomplishment at FDA and NSC to this new role; where she'll continue to advance innovation, science, and public health.

**B BioCentury** @BioCentury

Luciana Borio (@lborio) joins Arch as venture partner, brings expertise, FDA, White House experience in biodefense and public health and will focus on manufacturing, clinical trials, novel therapies. Firm promotes Carol Suh to partner [buff.ly/3zIRFWX](https://buff.ly/3zIRFWX)

11:46 PM · Jul 23, 2021



62



See the latest COVID-19 information on Twitter

On November 9, 2020, [U.S. president-elect Joe Biden](#) named Borio to be one of the 13 members of his [COVID-19 Advisory Board](#).<sup>[9]</sup>

activities for the Office of Preparedness and Response.<sup>[12]</sup> Before leaving her role as assistant commissioner of FDA, she approved a partnership in infectious disease research with the [Bill & Melinda Gates Foundation](#).<sup>[13]</sup>

In 2020, Borio was appointed by the [Council on Foreign Relations](#) to serve on its Independent Task Force on Improving Pandemic Preparedness, co-chaired by [Sylvia Mathews Burwell](#) and [Frances Townsend](#).<sup>[14]</sup>

## Other activities [\[ edit \]](#)

- Codagenix, Member of the Scientific Advisory Board<sup>[15]</sup>
- [Goldman Sachs](#), Consultant<sup>[16]</sup>



SCOTT GOTTLIEB



FDA



Illumina



Pfizer



CNBC



Action



Resilience



Gottlieb: There will be a rapid acceleration of coronavirus cases in US

192K views • 4 years ago



CNBC Television

Dr. Luciana Borio, vice president of In-Q-Tel and former Director of Medical and Biodefense Preparedness policy for the White ...

MARKET  
SELL-OFF

GLOBAL MARKETS ROUTED

CNBC  
8:00

WSJ **OPINION** JAN 28 2020

English Edition | January 29, 2020 | Print Edition |

Home World U.S. Politics Economy Business Tech Markets **Opinion** Life & Arts Real Estate WSJ. Magazine

OPINION | COMMENTARY

# Act Now to Prevent an American Epidemic

Quarantines, flu vaccines and other steps to take before the Wuhan virus becomes widespread.

By Luciana Borio and Scott Gottlieb

Jan. 28, 2020 6:48 pm ET



PRINT



TEXT

105



## GOTTLIEB & LUCIANA BORIO

ENDPOINTSNEWS

CHANNELS

WEBINARS

BIOPHARMA JOBS

MORE



Luciana Borio (Susan Walsh/AP Images)

July 26, 2021 10:44 AM EDT Updated 03:38 PM People

Bob Nelsen's ARCH adds FDA, biodefense expertise with appointment of Luciana Borio

### TRENDING NOW

Biogen makes its move, announcing a \$7.3B deal for Reata

AstraZeneca picks up Pfizer's rare disease gene therapies, taps new R&D leader as Mene Pangalos steps down

Sanofi, BioNTech cut early-stage mRNA cancer therapy from pipeline

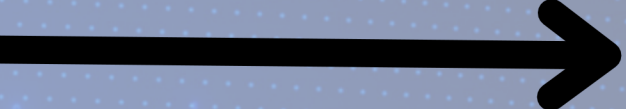
'This is not a science problem anymore': Paths emerge for scaling up rare disease medicine

Pharma giants tout AI tools as high priority in half-year earnings reports

### SPONSORED

Save Time and Up to 43.5% on Clinical Trial Spend Conducting Australian and US Trials





**MODERNA TASKED RESILIENCE TO PRODUCE ITS C19 INJECTION**

**AT THE TOP OF THE BOARD OF DIRECTORS IS THE MAN WHO'S IDEA RESILIENCE CAME FROM IS ROBERT NELSEN**

**WHO MADE ROBERT NELSEN THE HEAD OF THE BOARD OF DIRECTORS**



**NELSEN OWNS ARCH A COMPANY THAT HAS ON ITS BOARD LUCIANA BORIO, WHOM NELSEN CREDITS WITH INSPIRING RESILIENCE.**

**BORIO IS ALSO A JOHNS HOPKINS GRAD, FORMER FDA CHIEF SCIENTIST, AND SHE SITS ON THE COUNCIL ON FOREIGN RELATIONS WITH HER LONG TIME PAL NELSEN**



- Resilience was founded in 2020 by Drew Oetting, Patrick Yang, Sandesh Mahatme, and Rahul Singhvi. 1 2 3 4 5





## Implications for outbreak management

Mike Ryan, MD, the WHO's executive director of emergency programs, told reporters that the WHO welcomes the results and he praised all of the Ebola workers, including the ones working on the infrastructure that allows doctors and nurses to deliver the treatments.

However, he said the tragedy is that not enough people are being treated and not enough people are coming to the hospital. "There are outstanding results for people who seek care early."

Earlier in the outbreak, an ethics committee in the DRC approved the four experimental treatments for compassionate use, and patients at all of the country's Ebola treatment centers have had access to them, along with safety monitoring. However, the formal clinical trial has been under way since November at four treatment centers with the help of the Alliance for International Medical Action (ALIMA), the International Medical Corps (IMC), and Doctors Without Borders (MSF).

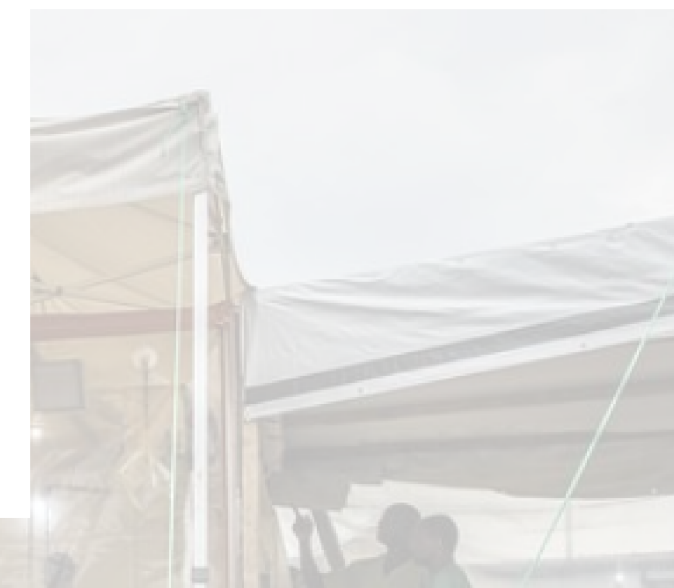
At a media telebriefing today, Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID), said Regeneron was the drug that crossed the efficacy threshold, triggering a pause in the study. And he said the group recommended proceeding with mAb 114, because there were only small differences in the data between the two drugs.

He said the findings of the study are a "ringing endorsement" that ethical and scientifically sound research can be conducted in an outbreak setting.

Jean Jacques Meyumbe Tamfum, PhD, an Ebola expert who was recently appointed to head a group that is now leading the DRC's Ebola response, said he was grateful for the support of international partners, who are working in an extremely difficult setting. "We can no longer say that Ebola virus disease is not curable."

In other outbreak developments, the DRC reported 38 more cases since Aug 9, lifting the outbreak total past 2,800 to 2,831.

<https://www.cidrap.umn.edu/ebola/ebola-outbreak-treatment-trial-narrowed-two-promising-drugs>



# Richard Hatchett

1 language

Article [Talk](#)

[Read](#) [Edit](#) [View history](#) [Tools](#)

From Wikipedia, the free encyclopedia

(Redirected from [Richard J. Hatchett](#))

**Richard Hatchett** is an American oncologist<sup>[1]</sup> and epidemiologist who has been serving as [chief executive officer](#) of the [Coalition for Epidemic Preparedness Innovations](#) (CEPI) in Oslo and London since 2017.<sup>[2][3]</sup> He was awarded the [Secretary of Health and Human Services's](#) Award for Distinguished Service.<sup>[4]</sup>

## Early life and education [\[ edit \]](#)

Hatchett grew up in [Alabama](#).<sup>[5]</sup> He graduated from [Vanderbilt University](#) and [Vanderbilt University School of Medicine](#).<sup>[6]</sup> He completed an internship and residency in Internal Medicine at [New York Hospital – Cornell Medical Center](#), and a fellowship in Medical Oncology at the [Duke University Hospital](#).<sup>[7]</sup> He was also a research associate at the National Heart & Lung Institute at [Imperial College London](#) and spent three months in northeast [Gabon](#) investigating three closely related [Ebola](#) outbreaks.<sup>[8]</sup>



Dr Richard J. Hatchett (2011)

## Richard Hatchett:

[Vanderbilt Univ.,](#)  
**Cornell, & Duke**

**Suspected Former CIA**  
**Former [BARDA](#)**  
**Current [CEO](#) at CEPI**





# Richard Hatchett:



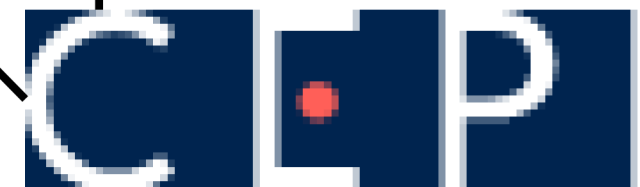
Hatchett was the Chief Medical Officer and deputy director of the United States [Biomedical Advanced Research and Development Authority](#) (BARDA) from 2011 to 2016 before becoming the organization's acting Director in 2016.<sup>[20]</sup> At BARDA, he oversaw programs to develop medical countermeasures against chemical, biological, radiological and nuclear threats, pandemic influenza, and emerging infectious diseases and led or helped lead the development of vaccines, therapeutics and diagnostics for a number of emerging viruses, including the H3N2v and H7N9 [influenza](#) viruses, [MERS](#), [Ebola](#) and [Zika](#).<sup>[21]</sup>

## CEO of CEPI, 2017–present [\[ edit \]](#)

In 2017, Hatchett was appointed as CEO of the Coalition for Epidemic Preparedness Innovations, succeeding interim CEO [John-Arne Røttingen](#).<sup>[22]</sup> In May 2020, amid the [COVID-19 pandemic](#), he was appointed to the expert advisory group for the UK Government's Vaccine Task Force.<sup>[23]</sup> When the UK held the rotating presidency of the [Group of Seven](#) (G7) in 2021, the government also appointed him to serve as a member of the Pandemic Preparedness Partnership, chaired by [Patrick Vallance](#).<sup>[24][25]</sup>

Under Hatchett's leadership, CEPI funded early development of [COVID-19](#) candidate vaccines. CEPI also teamed up with the [African Union](#) to fund African vaccine production.<sup>[26][27]</sup> Together with [Seth Berkley](#), he developed the concept for [COVAX](#) in early 2020.<sup>[28]</sup> CEPI is organizing a 2022 Covid summit.<sup>[29][30]</sup>

In March 2020, Hatchett warned about [COVID-19](#).<sup>[31]</sup> He does not think [Intellectual property](#) rights significantly contribute to [vaccine](#) shortages.<sup>[32][33]</sup> He is concerned about [supply chain](#) problems,<sup>[34][35]</sup> and [export controls](#).<sup>[36]</sup>





## Leadership

Scientific Advisory Committee

William H. Gates Sr.

Warren Buffett

**WATTENDORF JOINED DARPA IN 2010  
HE WAS A LEAD PROGENITOR OF THE  
MONOCLONAL  
ANTIBODY PROGRAMS AT DARPA**

**HE NOW WORKS FOR THE BILL AND  
MELINDA GATES FOUNDATION**



**Dan Wattendorf**

Director, Innovative Technology  
Solutions







# DR. JAMES CROWE



Dr. Crowe's lab delivered an antibody treatment to drugmaker AstraZeneca in a record 25 days. Others funded by the government's pandemic response program also shattered Matt Hepburn's 60-day mark, including biotech company AbCellera, working with Eli Lilly and Regeneron, which was used to treat President Trump.

Dr. James Crowe: This is the new normal. It's gonna be 60 days from here on out.

Well not quite yet - currently, antibodies are grown in a bioreactor like one at this Defense Department Rapid Response Plant in Florida. It'll take three weeks for this to produce 7,500 doses.

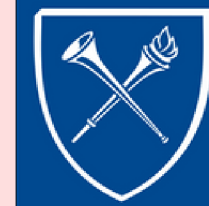
Dr. James Crowe: And so-- a lot of scientists are trying to figure out, can this be done faster?

Dr. Crowe has successfully tested a faster way: RNA, the genetic tool DARPA helped pioneer that was used to make the coronavirus vaccine in record time. In the next outbreak -- RNA would allow factories like this to churn out millions of doses a day



A

small-molecule antiviral discovered by Emory University researchers could soon start human testing against COVID-19, the respiratory coronavirus. That's the plan of Ridgeback Bio, which has licensed the compound, EIDD-2801, from an Emory nonprofit.

EMORY  
UNIVERSITY

EIDD-2801 works similarly to **Gilead Sciences' remdesivir**, an unapproved drug that was developed for the Ebola virus and is being tested as a treatment for COVID-19. Both molecules are nucleoside analogs that block RNA polymerase, an essential component of viral replication.



GILEAD

But remdesivir can only be given intravenously, meaning it would be difficult to deploy widely. In contrast, EIDD-2801 can be taken in pill form, says Mark Denison, a coronavirus expert and director of the infectious diseases division at Vanderbilt Medical School. Denison partnered with researchers at the University of North Carolina to test the compound against coronavirus.



EIDD-2801 has other promising features. Many **antivirals work** by introducing errors into the viral genome, but, unlike other viruses, coronaviruses can fix some mistakes. In lab experiments,



Gilead Sciences and supporting researchers and clinicians are working with health authorities from the World Health Organization and in China to establish a placebo-controlled study to determine whether remdesivir is safe and effective in treating 2019-nCoV.

“This is a prime example of how the research we are conducting at UAB plays a critical role in treating patients on a global scale and our contribution of substantial scientific advances.”

– Richard Whitley, M.D., UAB  
Distinguished Professor

“The collaboration between UAB, our colleagues at Southern Research, Vanderbilt University and the University of North Carolina, along with our pharmaceutical partner Gilead Sciences, is indicative of our collaborative approach to respond to outbreaks in real time, and in helping communities worldwide fight 2019-nCoV. This is a prime example of how the research we are conducting at UAB plays a critical role in treating patients on a global scale and our contribution of substantial scientific advances,” Whitley continued.

Whitley expressed that the potential for mutation of 2019-nCoV means that

Get the latest COVID-19 information at  
[uab.edu/coronavirus](https://uab.edu/coronavirus).

UAB’s AD3C and partners will need to build backup molecules for potential testing and treatment in the near future.

UAB is the lead institution for AD3C and research conducted; but the team unifies scientists experienced in virology, viral immunology, pathogenesis, medicinal chemistry and translation to human disease from UAB, University of North Carolina, Vanderbilt University, Emory University, Washington University, The University of Texas Medical Branch, Southern Research, the Emory Institute of Drug Discovery, the University of Colorado, Denver, and Oregon Health & Science University.

**[HTTPS://WWW.UAB.EDU/NEWS/HEALTH/ITEM/11082-INVESTIGATIONAL-COMPOUND-REMDESIVIR-DEVELOPED-BY-UAB-AND-NIH-RESEARCHERS-BEING-USED-FOR-TREATMENT-OF-NOVEL-CORONAVIRUS](https://www.uab.edu/news/health/item/11082-investigational-compound-remdesivir-developed-by-uab-and-nih-researchers-being-used-for-treatment-of-novel-coronavirus)**





*Med (N Y)*. 2022 Mar 11; 3(3): 188–203.e4. Published online 2022 Feb 3. doi: [10.1016/j.medj.2022.01.004](https://doi.org/10.1016/j.medj.2022.01.004)

PMCID: PMC8810411 | PMID: [35132398](https://pubmed.ncbi.nlm.nih.gov/35132398/)

## A combination of two human neutralizing antibodies prevents SARS-CoV-2 infection in cynomolgus macaques

[Ronald R. Cobb](#),<sup>1,15</sup> [Joseph Nkolola](#),<sup>2,15</sup> [Pavlo Gilchuk](#),<sup>3,15</sup> [Abishek Chandrashekar](#),<sup>2</sup> [Jingyou Yu](#),<sup>2</sup> [Robert V. House](#),<sup>4</sup> [Christopher G. Earnhart](#),<sup>5</sup> [Nicole M. Dorsey](#),<sup>5</sup> [Svetlana A. Hopkins](#),<sup>6</sup> [Doris M. Snow](#),<sup>4</sup> [Rita E. Chen](#),<sup>7,8</sup> [Laura A. VanBlargan](#),<sup>7</sup> [Manuel Hechenblaickner](#),<sup>1</sup> [Brian Hoppe](#),<sup>1</sup> [Laura Collins](#),<sup>1</sup> [Milan T. Tomic](#),<sup>9</sup> [Genevieve H. Nonet](#),<sup>9</sup> [Kyal Hackett](#),<sup>4</sup> [James C. Slaughter](#),<sup>10</sup> [Mark G. Lewis](#),<sup>11</sup> [Hanne Andersen](#),<sup>11</sup> [Anthony Cook](#),<sup>11</sup> [Michael S. Diamond](#),<sup>7,8,12</sup> [Robert H. Carnahan](#),<sup>3,13</sup> [Dan H. Barouch](#),<sup>2,\*</sup> and [James E. Crowe, Jr.](#)<sup>3,13,14,16,\*\*</sup>



[Kyal Hackett](#),<sup>4</sup> [James C. Slaughter](#),<sup>10</sup> [Mark G. Lewis](#),<sup>11</sup> [Hanne Andersen](#),<sup>11</sup> [Anthony Cook](#),<sup>11</sup> [Michael S. Diamond](#),<sup>7,8,12</sup> [Robert H. Carnahan](#),<sup>3,13</sup> [Dan H. Barouch](#),<sup>2,\*</sup> and [James E. Crowe, Jr.](#)<sup>3,13,14,16,\*\*</sup>

▼ [Author information](#) ► [Article notes](#) ► [Copyright and License information](#) [PMC Disclaimer](#)

<sup>1</sup>Ology Bioservices, Process Development and Manufacturing, Alachua, FL 32615, USA

<sup>2</sup>Center for Virology and Vaccine Research, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA 02215, USA

<sup>3</sup>Vanderbilt Vaccine Center, Vanderbilt University Medical Center, Nashville, TN 37232, USA

<sup>4</sup>Ology Bioservices, Frederick, MD 21701, USA

<sup>5</sup>Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, US Department of Defense, Frederick, MD 21703, USA

<sup>6</sup>Logistics Management Institute (LMI), Tysons, VA 22102, USA

<sup>7</sup>Department of Medicine, Washington University School of Medicine, St. Louis, MO 63110, USA

<sup>8</sup>Department of Pathology & Immunology, Washington University School of Medicine, St. Louis, MO 63110, USA

<sup>9</sup>Research and Development, Ology Bioservices, Inc., Alameda 94501, CA, USA

<sup>10</sup>Department of Biostatistics, Vanderbilt University Medical Center, Nashville, TN 37232, USA

<sup>11</sup>Bioqual, Inc., Rockville, MD 20850, USA

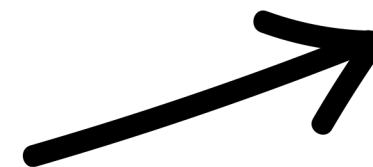
<sup>12</sup>Department of Molecular Microbiology, Washington University School of Medicine, St. Louis, MO 63110, USA

<sup>13</sup>Department of Pediatrics, Vanderbilt University Medical Center, Nashville, TN 37232, USA

<sup>14</sup>Department of Pathology, Microbiology, and Immunology, Vanderbilt University Medical Center, Nashville, TN 37232, USA

\*Corresponding author

**-2022-**  
**Dr. James Crowe**  
**[Vanderbilt] +**  
**the JPEO-CBRND**  
**& Ology Bioservices**



Contract ID:	HHSO100201300018I	Reference IDV:	-
Modification Number:	P00008	Transaction Number:	-
Award/IDV Type:	IDC Indefinite Delivery Contract	Action Obligation (\$):	\$0.00
Date Signed:	Nov 15, 2021	Solicitation Date:	-
Contracting Agency ID:	7505	Contracting Agency:	OFFICE OF ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Contracting Office Name:	BARDA - ASPR / DAAPPO / BARDA DCMA	PSC Type:	P
PSC:	6505	PSC Description:	DRUGS AND BIOLOGICALS
NAICS:	325414	NAICS Description:	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING
Entity City:	ALACHUA	Entity State:	FL
Entity ZIP Code:	326158726	Additional Reporting Code:	-
Additional Reporting Description:	-	Unique Entity ID:	GC2RFAZK8G64
Ultimate Parent Unique Entity ID:	GC2RFAZK8G64	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS INC.
Legal Business Name:	LOGY BIOSERVICES, INC.	CAGE Code:	3GQS9

Contract ID:	HHSO10033004T	Reference IDV:	HHSO100201300018I
Modification Number:	8	Transaction Number:	0
Award/IDV Type:	DO Delivery Order	Action Obligation (\$):	\$0.00
Date Signed:	May 18, 2018	Solicitation Date:	-
Contracting Agency ID:	7505	Contracting Agency:	OFFICE OF ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Contracting Office Name:	BARDA - ASPR / DAAPPO / BARDA DCMA	PSC Type:	P
PSC:	6505	PSC Description:	DRUGS AND BIOLOGICALS
NAICS:	325414	NAICS Description:	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING
Entity City:	ALACHUA	Entity State:	FL
Entity ZIP Code:	326158726	Additional Reporting Code:	-
Additional Reporting Description:	-	Unique Entity ID:	GC2RFAZK8G64
Ultimate Parent Unique Entity ID:	GC2RFAZK8G64	Ultimate Parent Legal Business Name:	NANOTHERAPEUTICS INC.
Legal Business Name:	LOGY BIOSERVICES, INC.	CAGE Code:	3GQS9

# Ology Bioservices /Resilience +BARDA + ASPR 2018-2021 Contracts

# ASPR

# RESILIENCE



<https://www.fpds.gov/ezsearch/fpdsportal?>

[s=ICD&indexName=awardfull&templateName=PDF&q=UEI\\_NAME%3A%22OLOGY+BIOSERVICES%2C+INC.%22+UEI\\_NAME%3A%22OLOGY+BIOSERVICES%2C+IN](https://www.fpds.gov/ezsearch/fpdsportal?s=ICD&indexName=awardfull&templateName=PDF&q=UEI_NAME%3A%22OLOGY+BIOSERVICES%2C+INC.%22+UEI_NAME%3A%22OLOGY+BIOSERVICES%2C+IN)

Supaporn's research on bats has made her a giant in the field of virus discovery worldwide. She's caught the attention — and funding — of the US government, which funded her research through the US Agency for International Development or USAID and even through the Defense Advanced Research Projects Agency or DARPA, the Department of Defense's research arm.

"I work with some of the global leaders on virologic expeditions and I consider Chu at the very top of my list," said Dr. Michael Callahan, a US government clinical infectious disease specialist and the founder of DARPA's Prophecy program, which monitors and predicts virus evolution around the globe in order to prevent and contain outbreaks before they become pandemics.

Without her tireless work ethic and ability to navigate the needs of different governments and the worldwide scientific community, Callahan said, the US government would not have been able to work in Thailand on critically important global virology projects.





The NEW ENGLAND  
JOURNAL of MEDICINE

PERSPECTIVE



# Developing Safe and Effective Covid Vaccines — Operation Warp Speed's Strategy and Approach

**Authors:** Moncef Slaoui, Ph.D., and Matthew Hepburn,  
M.D. [Author Info & Affiliations](#)

Published August 26, 2020 | N Engl J Med 2020;383:1701-1703

DOI: 10.1056/NEJMp2027405 | [VOL. 383 NO. 18](#)

# HEADS OF OWS:

## MONCEF SLAOUI

## MATTHEW HEPBURN [DARPA]

HEPBURN LEAD THE **ADEPT** PROGRAM  
SLAOUI WAS ON THE BOARD FOR GSK,  
& JOINED **MODERNA**'S BOARD OF  
DIRECTORS IN 2017

Moncef Slaoui



Slaoui with [GlaxoSmithKline](#) CEO [Emma Walmsley](#) (December 2016)

### Corporate directorships [\[edit\]](#)

In July 2017, he joined [Moderna](#)'s Board of Directors.<sup>[29]</sup>

[HTTPS://WWW.NEJM.ORG/DOI/10.1056/NEJMP2027405](https://www.nejm.org/doi/10.1056/NEJMP2027405)



*Summer 2021 / Volume V, Number 2*



## Inside Operation Warp Speed: A New Model for Industrial Policy

*by David Adler*

Operation Warp Speed<sup>1</sup> (OWS) was launched on May 15, 2020. A partnership between the Departments of Health and Human Services (HHS) and Defense (DoD), other agencies, and the private sector, its goal was to “accelerate the testing, supply, development, and distribution of safe and effective vaccines, therapeutics, and diagnostics to counter Covid-19.” As a result of OWS, millions of lives were saved from the pandemic.



[HTTPS://ARCHIVE.IS/L3NIV](https://archive.is/L3NIV)



## OWS AND VACCINE DEVELOPMENT

Slaoui and Hepburn published an article in the *New England Journal of Medicine* in October 2020 in which they explained OWS's strategy for vaccine development: "We sought to build a diverse project portfolio that includes two vaccine candidates based on each of the four platform technologies."<sup>9</sup> Core to OWS's acceleration strategy was to run vaccine development processes in parallel rather than sequentially. Almost from the outset, OWS took on the unprecedented financial risk of funding and scaling up manufacturing efforts while the vaccine candidates were still in clinical trials.

To choose from over a hundred vaccine candidates, OWS used "down select," according to Hepburn, meaning whittling down the list using objective criteria. "The goal was never to try to pick one type of vaccine technology, let alone one company, but instead to keep the portfolio diverse. This was very deliberate given the many unknowns," he says. Vaccine candidates had to use one of the three platform technologies deemed most promising. They were further selected on the basis of clinical trial data and other formalized criteria, including their potential for scalability in manufacturing. In the end, three vaccine platforms, and two companies per platform, were targeted: (1) mRNA: Moderna, Pfizer/BioNTech; (2) replication-defective live-vector platform: AstraZeneca, Janssen; (3) recombinant-subunit-adjuvanted protein: Novavax, Sanofi/GSK.



OWS heavily invested in R&D for these vaccine candidates. Pfizer was an outlier in that OWS did not fund development or manufacturing, but it did place a roughly a \$2 billion order for a hundred million doses, contingent upon FDA approval or authorization of the vaccine. Pfizer's CEO said the reason for this structuring was to "liberate" the company from government bureaucracy. Another unstated but possible motive was to immunize Pfizer's intellectual property from public claims related to federally funded research. Notably, moreover, Pfizer's partner BioNTech received \$445 million in funding for development and scale-up manufacturing from the German government.<sup>12</sup>

Moderna designed its vaccine in just two days, demonstrating the power of mRNA technology. It produced an actual vaccine that could be tested on humans in sixty-three days. Nevertheless, Moderna, unlike Pfizer, lacked deep expertise at running clinical trials, and faced the problem of too few minority volunteers. Here the NIH stepped in to help. OWS pursued a strategy of running clinical trials concurrently rather than sequentially, saving significant time.

**[HTTPS://ARCHIVE.IS/L3NIV](https://archive.is/L3NIV)**



Dr. Michael Callahan, an infectious disease specialist at Massachusetts General Hospital and Harvard Medical School, explains just how radical these results were, including the novel technology and development efforts that led to them: “mRNA-based protein expression is the most recent interesting American invention,” Callahan says. “Warp Speed could not have happened if the technology had not been developed to move this quickly. We got very lucky with mRNA.” With mRNA, scientists only need to know the sequence of the virus to design a vaccine. Sequence data was provided by the Chinese in the first week of January 2020. China’s capabilities in this area are comparable to or better than America’s.



Callahan’s academic bio doesn’t convey the depth of his expertise. Callahan previously oversaw DARPA’s biodefense therapeutics portfolio, the “Accelerated Manufacture of Pharmaceuticals” (AMP) program, whose goal was to radically accelerate the manufacturing of protein vaccines, and sister programs “7 Day Biodefense” and “Prophecy” (to predict virus evolution). Callahan coordinated the world’s largest international medical evacuation from a hot zone, the repatriation of nearly four hundred Americans from the Covid-19-plagued *Diamond Princess* cruise ship, and emergency care of infected passengers on the *Grand Princess* cruise. He was then recruited as special adviser on Covid-19 to the assistant secretary of preparedness and response (ASPR), Robert Kadlec.

But there are potential risks, even controversies, related to OTs. They bring reduced transparency, and some exemptions from regulations designed to protect taxpayers. Specifically, the concern around OWS is that OTs might have allowed pharma companies to circumvent the Bayh-Dole Act,<sup>17</sup> which provides the public with rights in intellectual property arising out of federally funded research, including march-in rights.<sup>18</sup>

*EUA.* Emergency Use Authorization (EUA) is a mechanism to allow use of medical products without full FDA approval during a health emergency, such as a pandemic. Traditional FDA approval for a vaccine can take years, whereas an EUA is much quicker, though it still involves rigorous evaluation by the FDA. As the FDA notes, “efforts to speed vaccine development to address the ongoing Covid-19 pandemic have not sacrificed scientific standards, integrity of the vaccine review process, or safety.”<sup>19</sup>

The GAO, however, was slightly critical in its report assessing the use of EUAs during the pandemic. Its study in no way argued that the authorized medicines weren’t safe, but rather that “the FDA does not uniformly disclose its scientific review of safety and effectiveness data for EUAs,” as it does for traditional approvals.<sup>20</sup>



[HTTPS://ARCHIVE.IS/L3NIV](https://archive.is/L3NIV)

Someone still had to make hundreds of millions of doses of mRNA, however, and very few companies had this expertise. Moderna already operated an existing advanced biotech manufacturing facility, but more production capacity was required. Moderna partnered with the contract manufacturer Lonza in May 2020,<sup>27</sup> long before its vaccine received an EUA. With funding provided by OWS through BARDA, the companies established mRNA manufacturing lines at Lonza’s factories in the United States and Switzerland.



Admiral Brett P. Giroir, MD, assistant secretary of HHS, took on the role of coordinating Covid-19 diagnostic testing in March 2020. He explains some of the challenges facing the United States: “We didn’t have a stockpile of tests or basic materials, and very little domestic manufacturing capacity. We had to scramble to import basic materials like swabs and pipette tips while we jump-started domestic production. There were no rapid tests, only PCR tests that required sophisticated laboratories.” Admiral Giroir began flying in one 747 a week filled just with swabs and similar basic materials from Europe.

Admiral Giroir, who earlier had directed the Defense Sciences Office at DARPA, implemented private-public partnerships to scale the manufacturing of tests. The government invested billions of dollars to build domestic test manufacturing capacity. By June 2020, the United States was testing five hundred thousand people daily.

In terms of vaccine production, OWS had been working with companies to scale up manufacturing almost from inception, when vaccine candidates were still only in preclinical trials. Slaoui and Hepburn, in their *NEJM* article, described some of the ways OWS offered technical support for the rapid scaling of manufacturing:

To ensure that industrial processes are set, running, and validated for FDA inspection when phase 3 trials end, OWS is supporting facility building or refurbishing, equipment fitting, staff hiring and training, raw-material sourcing, technology transfer and validation, bulk product processing into vials, and acquisition of ample vials, syringes, and needles for each vaccine candidate.<sup>[26](#)</sup>





Previous DARPA investments are also showing promise in combating COVID-19. For example, in 2013, the [Autonomous Diagnostics to Enable Prevention and Therapeutics](#) (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. The company used that technology to develop its COVID-19 vaccine, currently undergoing [Phase I clinical trials](#) in conjunction with NIH.

These DARPA programs are part of a broader biodefense effort to address threats that include naturally occurring epidemics, as well as accidental biological exposures, biowarfare, and bioterrorism. The nation's biodefense enterprise is distributed, spanning multiple departments and agencies with different missions, making preparing for and responding to a diverse and evolving set of biological threats challenging. In 2016, Congress directed the Secretaries of Health and Human Services (HHS), Defense, Homeland Security, and Agriculture to jointly develop a national biodefense strategy and associated implementation plan (P.L. 114-328, Section 1086). Issued in September 2018, the [National Biodefense Strategy](#) (with an implementation plan in Annex I) calls for the integration of biodefense R&D into federal planning, emphasizing the development of procedures and policies for interagency coordination of R&D efforts associated with responding to a biological incident. While the plan also calls for the sustainment of a robust national science and technology base to support biodefense, it does not articulate a need for interagency R&D planning and coordination. In 2015, the Blue Ribbon Study Panel on Biodefense, now the [Bipartisan Commission on Biodefense](#), highlighted military-civilian collaboration in biological R&D as one of many issues that “deserve more congressional oversight.”

The Biological Technologies Office currently supports a number of [programs that address pandemics](#). Since the emergence of COVID-19, DARPA has shifted the efforts of many of these programs to focus specifically on the coronavirus pandemic. [According to DARPA](#),

There is currently a mismatch between the rapidity at which biological threats can emerge and proliferate and the response time for developing and deploying effective medical countermeasures.... Cognizant of the need for speed, DARPA began aggressively pursuing medical countermeasures research more than a decade ago with a focus on developing generalizable, virus-agnostic technologies that can address whatever threat emerges, rather than building a collection of one-off solutions.

Examples of current DARPA investments include the [Pandemic Prevention Platform \(P3\)](#) program, whose goal is to develop methods “capable of producing relevant numbers of doses against any known or previously unknown infectious threat within 60 days of identification of such a threat.” Awardees of the P3 program have been applying the results of their work to COVID-19. For example, a COVID-19 antibody treatment developed with support from DARPA by AbCellera Biologics, in partnership with Eli Lilly and the National Institutes of Health (NIH) Vaccine Research Center, began [human clinical trials in June 2020](#).

Additionally, an awardee from DARPA’s [Epigenetic Characterization and Observation \(ECHO\)](#) program, Fluidigm, in collaboration with a consortium of medical schools, is developing an [early detection test for SARS-CoV-2](#), the novel virus that causes COVID-19.

In its role as advisor to the Secretary of HHS, the [National Biodefense Science Board \(NBSB\)](#), stated that

R&D for technologies, platforms, and systems to develop new MCM [medical countermeasures] against Disease X in 28 days from the recognition of the outbreak, which NBSB recommends as [a]





**Congressional  
Research Service**

Informing the legislative debate since 1914

**INSIGHT**

# DARPA's Pandemic-Related Programs

June 30, 2020

The [Defense Advanced Research Projects Agency \(DARPA\)](#) has contributed to the development of important military and commercial technologies, including stealth and personal electronics. DARPA's role and investments in defense-related research and development (R&D), including biological defense, has potential significance for the science and technology available to address the Coronavirus Disease 2019 (COVID-19) pandemic and any future biological threats. Advances in genome sequencing and editing, along with the application of engineering principles and computing and information sciences to the field of biology, have created opportunities to accelerate and expand the development of biotechnology products and processes. Although DARPA has invested in biological research since its establishment in 1958, in 2014 the agency created the [Biological Technologies Office](#), which focuses specifically on the biological sciences and biotechnology.



# Nathan Wolfe

Article [Talk](#)

From Wikipedia, the free encyclopedia

**Nathan Daniel Wolfe** (born 24 August 1970) is an American [virologist](#). He was the founder (in 2007) and director of [Global Viral](#)<sup>[1]</sup> and the [Lorry I. Lokey](#) Visiting Professor in Human Biology at [Stanford University](#).

## Career  [[edit](#)]

Wolfe spent over eight years conducting biomedical research in both [sub-Saharan Africa](#) and Southeast Asia. He is also the founder of [Metabiota](#), which offers both governmental and corporate services for biological threat evaluation and management. He serves on the editorial board of [EcoHealth](#) and [Scientific American](#) and is a member of [DARPA's](#) Defense Science Research Council. His laboratory was among the first to discover and describe the [Simian foamy virus](#).<sup>[2]</sup>

In 2008, he warned that the world was not ready for a pandemic.<sup>[3]</sup>

In 2011, his book *The Viral Storm: The Dawn of a New Pandemic Age*<sup>[4]</sup> was short-listed for the [Winton Prize](#).<sup>[5]</sup>

As reported in a *Wired* feature in 2020, Wolfe worked with the German insurance firm [Munich Re](#) to offer major corporate leaders pandemic policies, which were not purchased; a stark reality during the ensuing [COVID-19 pandemic](#).<sup>[6]</sup>

## Awards  [[edit](#)]

Wolfe has been awarded more than \$40 million in funding from a diverse array of sources including the [U.S. Department of Defense](#), [Google.org](#), the [National Institutes of Health](#), the [Skoll Foundation](#), the [Bill & Melinda Gates Foundation](#) and the [National Geographic Society](#).<sup>[7]</sup>

- Fulbright fellowship recipient (1997)
- [National Geographic](#) Emerging Explorer (2004)<sup>[2]</sup>
- NIH Director's Pioneer Award (2005)
- Popular Science*: "Brilliant 10" (2006)
- Rolling Stone*: "Top 100 Agents of Change" (2009)
- [World Economic Forum's Young Global Leaders](#) (2010)

🌐 3 languages ▼

[Read](#) [Edit](#) [View history](#) [Tools](#) ▼

Nathan D. Wolfe



Wolfe in 2011

<b>Born</b>	August 24, 1970 (age 53) <div><span></span> <a href="#">Detroit, Michigan</a>, U.S.</div>
<b>Citizenship</b>	<span><span></span></span> United States
<b>Alma mater</b>	<span><span></span></span> Stanford, <a href="#">Harvard</a>
<b>Scientific career</b>	
<b>Fields</b>	<a href="#">Virology</a>
<b>Institutions</b>	<a href="#">Stanford</a> , <a href="#">UCLA</a>

# NATHAN WOLFE

## Ecohealth Alliance

## Collaborator with

## DARPA, DoD, Google, NIH, Skoll,& The Bill & Melinda Gates Foundation

Wolfe founded Metabiota; a company that is funded by **In-Q-Tel [CIA]** since 2017 and as of 2019 Metabiota was the 3rd largest contract for IQT.

In 2014 **HunterBiden** bought a **14% stake** in the company.

Metabiota has ties to the Pentagon funded Biolabs in Ukraine.

Metabiota was also funded under **USAID [CIA]** alongside **EcoHealth** in the year leading up to the Pandemic



## George Painter, PhD



George Painter, Ph.D., is a professor in the Department of Pharmacology and Chemical Biology at Emory University School of Medicine, CEO of the Drug Innovation Ventures at Emory (DRIVE), and director of the Emory Institute for Drug Development. Dr. Painter has decades of experience in the discovery and development of pharmaceutical agents for the biotechnology and global pharmaceutical sectors. Within three years of its start, DRIVE discovered and licensed an antiviral agent to a major pharmaceutical firm and secured two major federal antiviral drug development contracts. Over the last 30 years, he has played a major role in the discovery, development, and implementation of modern antiviral therapy.

Before coming to Emory in 2012, Dr. Painter cofounded and led the biotechnology firm Chimerix, Inc. During his tenure there, he led the development of a drug for the prevention and treatment of adenovirus infection in stem cell transplant patients, a previously untreatable and often fatal infection in children. Before Chimerix, he was a founding member of the management team of Triangle, Inc., where he led the development of the now widely used HIV drug, Emtriva. In 2002, Triangle was sold to Gilead Sciences.

Prior to entering the biotech sector, Dr. Painter held senior management positions in large pharmaceutical companies including Burroughs Wellcome Co and what is now GlaxoSmithKline, where he led the discovery, development, and commercialization of antiviral agents to treat HIV and Hepatitis B. He holds more than 150 patents, many of which have led to approved, commercially available drugs or combinations of drugs for the treatment of HIV, Hepatitis B, smallpox, and coronavirus infections. He has published more than 120 peer-reviewed papers. Dr. Painter earned his BS in Chemistry, MS in Physical Organic Chemistry, and Ph.D. in Organic Chemistry at Emory. He was a post-doctoral fellow at the California Institute of Technology.



<https://ridgebackbio.com/about/development-advisory-board/george-painter-phd/>



ORGANIZATION

# Triangle Pharmaceuticals

Summary

Financials

People

Technology

## About

Triangle Pharmaceuticals focus on potential therapies for the human immunodeficiency virus (HIV), including AIDS, and the hepatitis B virus

Acquired by



Durham, North Carolina, United States

101-250

Pre-Seed

Private

500,868

## Highlights

Investors

2



Similar  
Companies

3



Industries

Biotechnology

Health Care

Medical

Founded Date  
1995

Operating Status  
Active

Headquarters Regions

Research Triangle, East Coast, Southern US

Founders

Karl Hostetler

Last Funding Type

Pre-Seed

<https://www.crunchbase.com/organization/triangle-pharmaceuticals>



**By READDI, May 20th, 2022** – The National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, awarded the UNC Gillings School of Global Public Health and the UNC Eshelman School of Pharmacy a \$65 million grant, establishing an Antiviral Drug Discovery Center to develop oral antivirals that can combat pandemic-level viruses like COVID-19.

The center builds upon and is tightly affiliated with Carolina's Rapidly Emerging Antiviral Drug Development Initiative, or READDI.

The READDI-AViDD Center (READDI-AC), one of nine established by the NIH, is an integrated public-private partnership with a renowned, interdisciplinary research team of experts from the Gillings and Eshelman schools, as well as UNC School of Medicine. They will apply cutting-edge technologies to develop oral therapies that target viral families with high potential to cause a pandemic in the future.

READDI was initially founded and supported through Carolina's Creativity Hubs initiative and the Eshelman Institute for Innovation. Recent funding from the North Carolina General Assembly and support from several members of the North Carolina Congressional delegation have been critical in aiding the team's work. By drawing on expertise and technology from academic and industry partners, including Janssen Pharmaceuticals, Takeda, Chimerix Inc. and Pardes Biosciences, READDI-AC will aid in the discovery and development of broad-spectrum antivirals that reduce the risk of severe illness and death from these highly contagious viruses.

“The devastating effects of the SARS-CoV-2 pandemic illustrates the critical need for new antiviral treatments for both existing and future viral disease threats,” said Mark Heise, professor of genetics at the School of Medicine and co-founder of READDI alongside Baric and Associate Professor of Microbiology and Immunology Nathaniel Moorman. “The READDI-AC Program is poised to significantly enhance our ability to treat existing threats while preparing for future viral disease outbreaks.”

The READDI-AC’s consortium of international collaborators also includes the University of Toronto, Diamond Light Source LTD, Sichting VU, Duke University, McGill University, Rutgers University, the University of Alberta, the University of Wisconsin-Madison, University College London, Vanderbilt University and Vanderbilt University Medical Center, the University of Pennsylvania, the University of Maryland-Baltimore County, Oregon Health and Science University, Janssen Pharmaceutica NV, the University of Colorado-Denver, and the University of Tennessee Health Science Center.

Research reported in this publication was supported by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health under Award Number U19AI171292. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

## EBANGA™

Ridgeback would like to acknowledge and thank our collaborators on the EBANGA™  
(ansuvimab-zykl, mAb114) development program:



National Institute of  
Allergy and  
Infectious Diseases



National Institutes of Health  
*Turning Discovery Into Health*



Frederick National Laboratory  
for Cancer Research  
sponsored by the National Cancer Institute



World Health  
Organization



International  
Medical Corps





# Lagevrio (molnupiravir)

Ridgeback would like to acknowledge and thank our collaborators on the Lagevrio (molnupiravir; EIDD-2801) development program:



EMORY  
UNIVERSITY



<https://ridgebackbio.com/about/collaborations/>

# Press Release

## Chimerix and BARDA Announce Contract Extension of \$13.0 Million for the Continued Development of Brincidofovir for Smallpox

DURHAM, N.C., Sept. 14, 2015 (GLOBE NEWSWIRE) – Chimerix, Inc. (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced an extension of its contract with the Biomedical Advanced Research and Development Authority (BARDA) for the development of the broad spectrum antiviral, brincidofovir, as a medical countermeasure to treat smallpox.

This latest contract extension provides an additional \$13.0 million to Chimerix for a period of 15 months. The company received an initial award from BARDA in February 2011 to support early research and development of brincidofovir in animal models of smallpox (Contract Number HHSO100201100013C) and received a contract extension of \$17.0 million in September 2014.



[Chimerix and BARDA Announce Contract Extension of \\$13.0 Million for the Continued Development of Brincidofovir for Smallpox](#)

# To focus on cancer, Chimerix sells rights to antiviral drug that defined the biotech

Chimerix is selling global rights to smallpox drug Tembexa, the biotech's only FDA-approved product, as a way to fund clinical development of a therapy in pivotal testing for a rare type of brain cancer. The deal marks Chimerix's nearly complete departure from the antiviral work that defined the company for most of its history.



By Frank Vinluan on May 16, 2022

Chimerix's first approved drug had several high-profile setbacks and ended up with a much narrower regulatory nod than initially hoped. Now the company is selling rights to that drug to Emergent BioSolutions as a way of raising cash as it looks ahead to a key late-stage trial for its lead asset, a drug that treats a rare type of cancer.

<https://medcitynews.com/2022/05/to-focus-on-cancer-chimerix-sells-rights-to-antiviral-drug-that-defined-the-biotech/>



Tembexa, the drug that Emergent is getting, was [approved](#) last June as a treatment for smallpox infection. Under a partnership with Biomedical Advanced Research and Development Authority (BARDA), Chimerix developed the antiviral as a medical countermeasure to protect against smallpox used as a biological weapon. For that application, the drug's customer base is essentially a single customer—BARDA. So far, Durham, North Carolina-based Chimerix has yet to record sales of the approved drug to the agency.



According to terms of the deal announced Monday, Emergent has agreed to pay Chimerix \$225 million when the deal closes, plus up to \$100 million more in up to four \$25 million milestone payments. Each of those milestone payments is tied to BARDA exercising procurement options on Tembexa. Chimerix said that it is in negotiations with BARDA on a procurement contract and will continue to lead that process until complete.



Had things worked out differently, Tembexa might have found wider use as a broad-spectrum antiviral. The drug, known for most of its history under the name brincidofovir, was hoped to offer advantages over an injectable Gilead Sciences antiviral, cidofovir. In addition to its pill formulation that is easier for patients to take, Chimerix had hoped brincidofovir would be safer than the Gilead drug, which is associated with kidney damage. The first indication Chimerix targeted was treating cytomegalovirus infections in transplant patients.

In 2009, during the early days of brincidofovir's clinical development, Chimerix also began making the drug available under the FDA's compassionate use program, which allows access to experimental therapies for patients who have no therapeutic options. As the antiviral progressed in clinical trials, Chimerix closed its compassionate use program to focus on pivotal tests of the drug that could support an application seeking FDA approval. But in 2014, Chimerix found itself in the midst of a [national debate about the "right to try" experimental drugs](#). A Virginia boy, Josh Hardy, was suffering from adenovirus infection following cancer treatment and a bone marrow transplant. His physicians recommended treatment with brincidofovir under compassionate use. The debate about access to the still experimental drug played out prominently in national news and social media. The company's CEO even received death threats.

<https://medcitynews.com/2022/05/to-focus-on-cancer-chimerix-sells-rights-to-antiviral-drug-that-defined-the-biotech/>

In 2019, Chimerix outlicensed global rights to brincidofovir to SymBio Pharmaceuticals for development in all human indications, except for orthopoxviruses, such as smallpox. Tokyo-based SymBio paid \$5 million up front and could pay up to \$180 million more if the drug achieves regulatory and commercial milestones. The deal put Chimerix in line for royalties from sales if SymBio commercializes the drug. According to the deal terms with Emergent, Chimerix is eligible to receive up to \$12.5 million in regulatory milestones stemming from SymBio's work with the drug.





# ERIK J. STEMMY

---



- **NIH PRINCIPLE INVESTIGATOR**
- **VIRAL (ARI) RESPIRATORY DISEASES BRANCH DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES, NIAID/NIH**



2023 Award Winner

**Erik Stemmy**

**STEMMY**

2023 Awards  
Summary

**1**

Group Award Won

## NIAID (National Institute of Allergy and Infectious Diseases)

Scientific/Medical - Research

Group Awards

[SARS-CoV-2 Assessment of Viral Evolution \(SAVE\) Program Group](#)

In recognition of significant contributions to the real-time assessment of emerging SARS-CoV-2 mutations that could impact transmissibility, virulence, and susceptibility to infection or vaccine-induced immunity.

**[HTTPS://DIRECTORSAWARDS.HR.NIH.GOV/AWARDS/2023/WINNERS/S/SAF04EFEF52FE037DC4438A43E0D567F/](https://directorsawards.hr.nih.gov/awards/2023/winners/s/saf04efef52fe037dc4438a43e0d567f/)**

Year	Occupation	Paygrade	Base Salary	Bonus	Location
2022	General Health Science	GS-14	\$155,687	\$0	Rockville, Maryland
2021	General Health Science	GS-14	\$151,118	\$0	Rockville, Maryland
2020	General Health Science	GS-14	\$145,578	\$0	Rockville, Maryland
2019	General Health Science	GS-14	\$136,725	\$0	Rockville, Maryland
2018	General Health Science	GS-14	\$129,869	\$0	Rockville, Maryland
2017	General Health Science	GS-14	\$126,958	\$0	Rockville, Maryland
2016	General Health Science	GS-14	\$116,146	\$0	Rockville, Maryland
2015	General Health Science	GS-14	\$110,902	\$0	Rockville, Maryland
2014	General Health Science	GS-13	\$89,924	\$0	Bethesda, Maryland

In 2022, Erik J. Stemmy was a [General Health Scientist](#) at the [National Institutes of Health](#) in Rockville, Maryland. Stemmy began working at the National Institutes of Health in 2011 with a starting salary of \$62,467. Since then, Stemmy's salary has increased to \$155,687 in 2022.

Erik J. Stemmy is a GS-14 under the [general schedule](#) payscale.



Erik J. Stemmy's 2022 pay is

↑ 36%

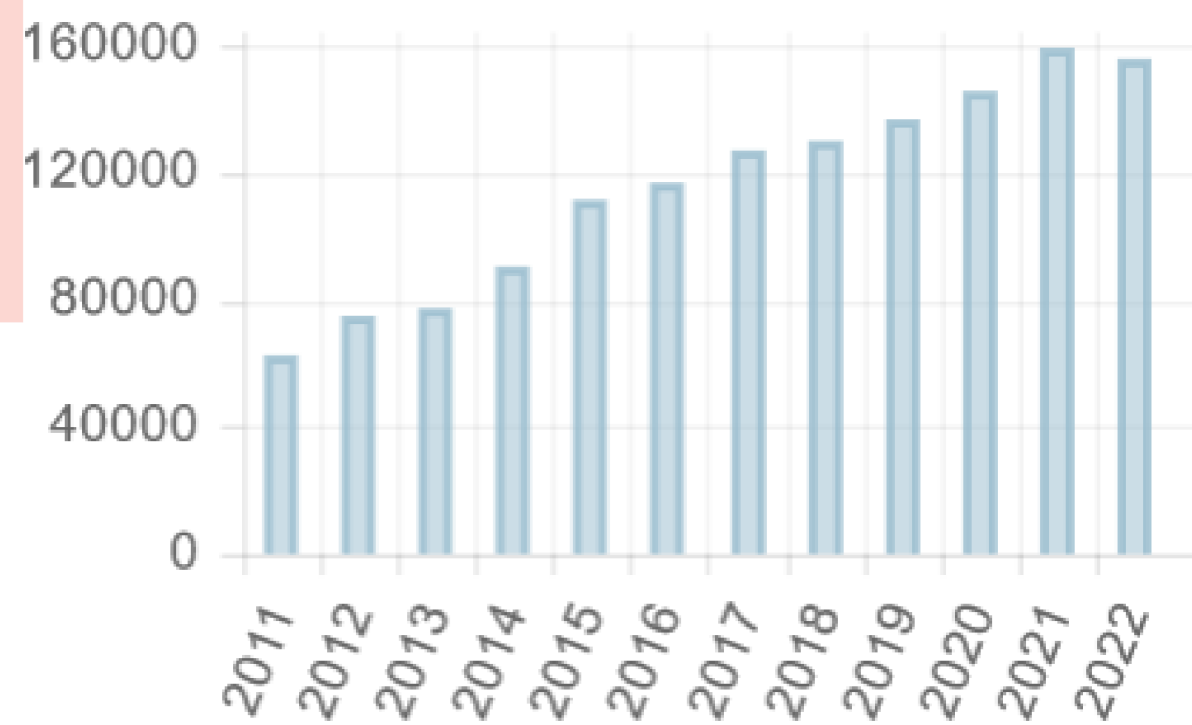
higher than the average **General Health Scientist** across all agencies.

Erik J. Stemmy's 2022 pay is

↑ 118%

higher than the average pay of a GS employee at the **National Institutes of Health**.

Erik J. Stemmy's pay trend during his or her government career in the National Institutes of Health:



**STEMMY**



**The George Washington University**

Ph.D., Immunology

2006 - 2011

Activities and societies: Institute for Biomedical Sciences

Dissertation topic: Characterizing the role of extracellular cyclophilins in chronic allergic asthma.



**Georgetown University**

M.S., Microbiology and Science Policy

2003 - 2005

## Licenses & certifications



**Certification for Contracting Officer's Representatives Level III (FAC-COR)**

United States Federal Government

Issued Aug 2018



## National Institute of Allergy and Infectious Diseases (NIAID)

Full-time · 13 yrs 2 mos

### Team Lead

Sep 2022 - Present · 1 yr 8 mos

Hybrid

Team Lead managing NIAID's Centers of Excellence for Influenza Research and Response (CEIRR) Network, a global multi-disciplinary network focused on understanding influenza natural history and pathogenesis. ...see more

🔒 Immunology, Research and +3 skills



### CEIRR Network

NIAID-funded Centers of Excellence for Influenza Research and Response Network

### Program Officer


Mar 2011 - Feb 2023 · 12 yrs

Program Officer in the Viral Respiratory Diseases Section of the Respiratory Diseases Branch in NIAID's Division of Microbiology and Infectious Diseases. I manage a diverse grant and contract research portfolio covering Rhinoviruses and Human Coronaviruses, including basic research, therapeutic & vaccine development, and pre/clinical testing. I also manage the Data Processing and Coordination Center for NIAID's Centers of Excellence for Influenza Research and Surveillance, a global network of researchers investigating influenza pathogenesis, transmission, and evolution.



https://grantome.com/search?q=erik+stemmy

STEMMY



[Search](#)[Advanced](#)[Reset](#)

[Help](#)

[Filter](#)[Reset](#)

Funder

Year

☐ 69

2020

☐ 29

2021

☐ 29

2018

☐ 28

2019

☐ 25

2014

☐ 24

2015

☐ 22

2016

☐ 20

2017

☐ 18

2013

☐ 18

2012

☐ 8

2010

Search

Show 10 entries

[Previous](#)[1](#)[2](#)[3](#)[4](#)[5](#)[...](#)[Next](#)

NIH 2021  
R00 AI

Structural Studies of the Coronavirus Life Cycle  
Kirchdoerfer, Robert Nicholas / University of Wisconsin Madison

NIH 2021  
R01 AI

Rational design and evaluation of novel mRNA vaccines against MERS-CoV  
Du, Lanying / New York Blood Center

NIH 2021  
R21 AI

Accelerating discovery of neutralizing paratopes with Functional Antibody Screening Technology  
De Figueiredo, Paul; Han, Arum / Texas A&M University

NIH 2021  
R21 AI

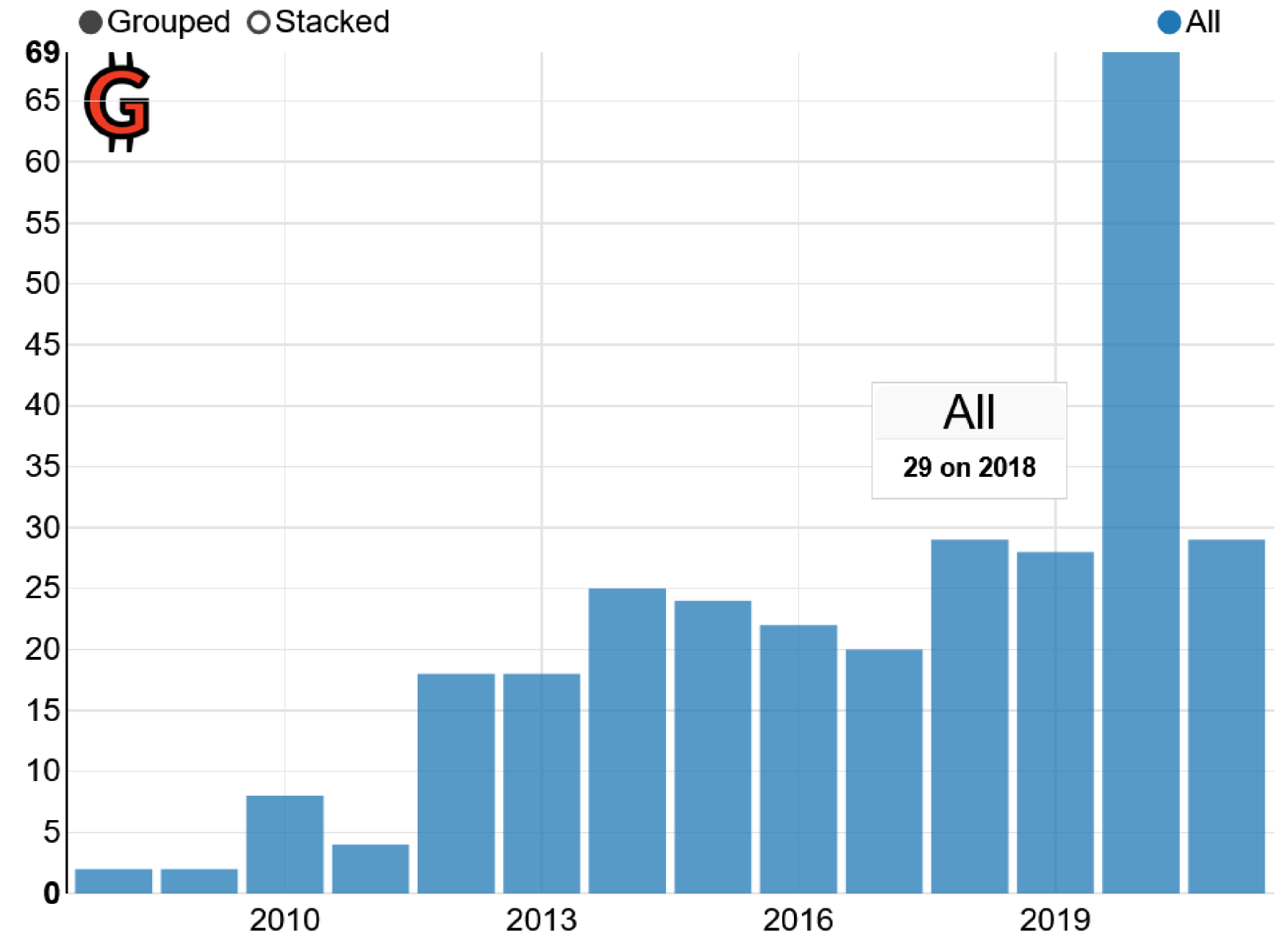
Rhinovirus C Infection in Normal and Asthmatic Human Airway Epithelium at Single Cell Resolution  
Scull, Margaret Adele; Rosenberg, Brad / University of Maryland College Park

<input type="checkbox"/>	10	Denison, Mark R.	←	Mark Denison	< Vanderbilt
<input type="checkbox"/>	22	Perlman, Stanley	←		
<input type="checkbox"/>	15	Li, Fang	←	Stanley Perlman	<Iowa
<input type="checkbox"/>	14	Makino, Shinji		Li Fang	< U Minn
<input type="checkbox"/>	12	Du, Lanying			
<input type="checkbox"/>	9	Sheahan, Timothy ...	←	Timothy Sheahan	<UNC
<input type="checkbox"/>	9	Baker, Susan C.			
<input type="checkbox"/>	8	Frieman, Matthew ...	←	Matthew Frieman	<Johns Hopkins
<input type="checkbox"/>	8	Hotez, Peter J.	←	Peter Hotez	
<input type="checkbox"/>	7	Kirchdoerfer, Robe...	←	Robert Kirchdoerfer	<UTMB
<input type="checkbox"/>	5	Daniel, Susan			<UW Madison
<input type="checkbox"/>	7	Bottazzi, Maria Ele...			
<input type="checkbox"/>	6	Weiss, Susan R.	←	Susan R. Weiss	< UPENN, UCSF
<input type="checkbox"/>	6	Daszak, Peter	←	Peter Daszak	<EHA
<input type="checkbox"/>	5	McLellan, Jason Sc...	←	Jason S. McLellan	<Johns Hopkins, VRC
<input type="checkbox"/>	5	Menachery, Vineet ...	←	Vineet Menachery	< UTMB & UNC
<input type="checkbox"/>	5	D'Souza, Victoria ...			
<input type="checkbox"/>	5	Harris, Eva			
<input type="checkbox"/>	5	Poehling, Katherin...			
<input type="checkbox"/>	4	Graepel, Kevin Whi...			

Authors on grant projects under **Stemmy**

<input type="checkbox"/>	24	University of Nort...
<input type="checkbox"/>	20	University of Iowa
<input type="checkbox"/>	19	Vanderbilt Univers...
<input type="checkbox"/>	13	University of Maryl...
<input type="checkbox"/>	12	New York Blood C...
<input type="checkbox"/>	11	University of Penn...
<input type="checkbox"/>	11	University of Texas...
<input type="checkbox"/>	9	Baylor College of ...
<input type="checkbox"/>	9	Loyola University ...
<input type="checkbox"/>	8	University of Wisc...
<input type="checkbox"/>	8	University of Minn...
<input type="checkbox"/>	8	Harvard University
<input type="checkbox"/>	7	University of Texas...
<input type="checkbox"/>	7	Cornell University
<input type="checkbox"/>	6	Ecohealth Alliance,...
<input type="checkbox"/>	5	University of Maryl...
<input type="checkbox"/>	5	University of Califo...
<input type="checkbox"/>	5	Wake Forest Unive...
<input type="checkbox"/>	4	Texas A&M Univer...
<input type="checkbox"/>	4	University of Texas...
<input type="checkbox"/>	4	Planet Biotechnolo...
<input type="checkbox"/>	4	Johns Hopkins Uni...
<input type="checkbox"/>	4	Wadsworth Center

<input type="checkbox"/>	3	Colorado State Uni...
<input type="checkbox"/>	3	University of Florida



**Stemmy was program lead on 20-29 grants annually from 2013-2019, then suddenly in 2020 that jumped over double the usual to 69 grants**


**STEMMY**



[nature](#) > [nature reviews microbiology](#) > [review articles](#) > [article](#)

Review Article | Published: 10 December 2018

# Origin and evolution of pathogenic coronaviruses

[Jie Cui](#), [Fang Li](#) & [Zheng-Li Shi](#) 

[Nature Reviews Microbiology](#) **17**, 181–192 (2019) | [Cite this article](#)

**371k** Accesses | **3254** Citations | **1509** Altmetric | [Metrics](#)

## Abstract

Severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) are two highly transmissible and



**Fang Li & the “bat Lady” Zheng-Li Shi**  
**December 2018**

- From: "David Morens" [redacted]@gmail.com>  
Sent: 7/13/2020 9:21:23 PM +0000  
To: "Keusch, Gerald T" [redacted]@bu.edu>  
CC: Peter Daszak [redacted]@ecohealthalliance.org>  
Subject: Re: PRO/AH/EDR> COVID-19 update (312): China, SARS-CoV2 origin, animal reservoir, WHO mission
- From: "David Morens" [redacted]@gmail.com>  
Sent: 4/26/2020 9:29:26 PM +0000  
To: "Keusch, Gerald T" [redacted]@bu.edu>  
CC: Peter Daszak [redacted]@ecohealthalliance.org>; Aleksei Chmura [redacted]@ecohealthalliance.org>  
Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Funding Agency

Agency National Institute of Health (NIH)  
Institute National Institute of Allergy and Infectious Diseases (NIAID)

Type Research Project (R01)  
Project # 2R01AI110964-06

Application # 9819304  
Study Section Clinical Research and Field Studies of Infectious Diseases  
Study Section (CRFS)

Program Officer Stemmy, Erik J

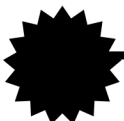
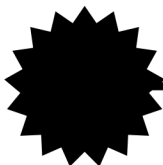
Project Start 2014-06-01  
Project End 2020-04-24  
Budget Start 2019-07-24  
Budget End 2020-04-24  
Support Year 6  
Fiscal Year 2019  
Total Cost  
Indirect Cost

Institution





















Name Ecohealth Alliance, Inc.  
Department  
Type  
DUNS # 077090066

City New York  
State NY  
Country United States  
Zip Code 10001






Erik Stemmy was the  
Program Officer for  
AI110964























EcoHealth Alliance

T Act Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC
<b>RBD recombinant protein-based SARS vaccine for biodefense</b>								
5	R01	AI098775-02	 <a href="#">HOTEZ, PETER J</a>  <a href="#">BOTTAZZI, MARIA ELENA</a>  <a href="#">JIANG, SHIBO</a> 	BAYLOR COLLEGE OF MEDICINE	2013	NIAID	NIAID	\$1,085,321
<b>Epidemiology and modeling of the population dynamics of influenza and antimicrobi</b>								
5	K01	AI101010-02	 <a href="#">GOLDSTEIN, EDWARD</a> 	HARVARD SCHOOL OF PUBLIC HEALTH	2013	NIAID	NIAID	\$126,873
<b>RBD recombinant protein-based SARS vaccine for biodefense</b>								
3	R01	AI098775-02S1	 <a href="#">HOTEZ, PETER J</a>  <a href="#">BOTTAZZI, MARIA ELENA</a>  <a href="#">JIANG, SHIBO</a> 	BAYLOR COLLEGE OF MEDICINE	2013	NIAID	NIAID	\$3,936
<b>Mechanisms of viral proteases in coronavirus replication and pathogenesis</b>								
5	R01	AI085089-04	 <a href="#">BAKER, SUSAN C.</a>  <a href="#">MESECAR, ANDREW D.</a> 	LOYOLA UNIVERSITY CHICAGO	2013	NIAID	NIAID	\$712,986
<b>Role of the Epithelial Growth Factor Receptor in SARS Coronavirus Pathogenesis</b>								
5	R01	AI095569-03	 <a href="#">FRIEMAN, MATTHEW</a> <a href="#">BRYAN</a> 	UNIVERSITY OF MARYLAND BALTIMORE	2013	NIAID	NIAID	\$485,623
<b>Epidemiology, transmission, and phylogenetics of influenza in a tropical country</b>								
5	U01	AI088654-04	 <a href="#">HARRIS, EVA</a>  <a href="#">GORDON, AUBREE L.</a> 	UNIVERSITY OF CALIFORNIA BERKELEY	2013	NIAID	NIAID	\$702,118
<b>Analysis of Coronavirus-Host Cell Interactions</b>								
5	R01	AI099107-02	 <a href="#">MAKINO, SHINJI</a> 	UNIVERSITY OF TEXAS MED BR GALVESTON	2013	NIAID	NIAID	\$359,550



Receptor recognition mechanisms of coronaviruses						
5 R01AI089728-04	 LI, FANG <a href="#">↗</a>	UNIVERSITY OF MINNESOTA	2013	NIAID	NIAID	\$351,302
Structure and Mechanism of Programmed Ribosomal Frameshifting in SARS coronavirus						
1 R01AI104711-01	 D'SOUZA, VICTORIA MANUEL <a href="#">↗</a>	HARVARD UNIVERSITY	2013	NIAID	NIAID	\$357,435
Determinants of Coronavirus Fidelity in Replication and Pathogenesis						
1 R01AI108197-01	 DENISON, MARK R <a href="#">↗</a>  BARIC, RALPH S <a href="#">↗</a>	VANDERBILT UNIVERSITY	2013	NIAID	NIAID	\$560,000
PPG: SARS-CoV-host cell interactions and vaccine development						
5 P01AI060699-08	 PERLMAN, STANLEY <a href="#">↗</a>	UNIVERSITY OF IOWA	2013	NIAID	NIAID	\$1,605,748
Evaluation of SARS-CoV 2'O Methyltransferase Mutants						
1 F32AI102561-01A1	 MENACHERY, VINEET D <a href="#">↗</a>	UNIV OF NORTH CAROLINA CHAPEL HILL	2013	NIAID	NIAID	\$52,190
Role of anti-SARS-CoV T cell response in pathogenesis						
5 R01AI091322-03	 PERLMAN, STANLEY <a href="#">↗</a>	UNIVERSITY OF IOWA	2013	NIAID	NIAID	\$354,850
Broad Spectrum Neutralizing Human Abs to SARS and Related Coronaviruses						
5 R01AI085524-04	 MARASCO, WAYNE A. <a href="#">↗</a>	DANA-FARBER CANCER INST	2013	NIAID	NIAID	\$1,025,389
Mechanisms of viral proteases in coronavirus replication and pathogenesis						
5 R01AI085089-05	 BAKER, SUSAN C. <a href="#">↗</a>  MESECAR, ANDREW D <a href="#">↗</a>	LOYOLA UNIVERSITY CHICAGO	2014	NIAID	NIAID	\$602,456

Understanding the Risk of Bat Coronavirus Emergence						
1 <a href="#">R01AI110964-01</a>	 <a href="#">DASZAK, PETER</a> 	ECOHEALTH ALLIANCE, INC.	2014	NIAID	NIAID	\$666,442
Role of anti-SARS-CoV T cell response in pathogenesis						
5 <a href="#">R01AI091322-04</a>	 <a href="#">PERLMAN, STANLEY</a> 	UNIVERSITY OF IOWA	2014	NIAID	NIAID	\$377,500
Receptor recognition mechanisms of coronaviruses						
5 <a href="#">R01AI089728-05</a>	 <a href="#">LI, FANG</a> 	UNIVERSITY OF MINNESOTA	2014	NIAID	NIAID	\$373,725
RBD recombinant protein-based SARS vaccine for biodefense						
5 <a href="#">R01AI098775-03</a>	 <a href="#">HOTEZ, PETER J</a>  <a href="#">BOTTAZZI, MARIA ELENA</a>  <a href="#">JIANG, SHIBO</a> 	BAYLOR COLLEGE OF MEDICINE	2014	NIAID	NIAID	\$1,134,359
Role of the Epithelial Growth Factor Receptor in SARS Coronavirus Pathogenesis						
5 <a href="#">R01AI095569-04</a>	 <a href="#">FRIEMAN, MATTHEW BRYAN</a> 	UNIVERSITY OF MARYLAND BALTIMORE	2014	NIAID	NIAID	\$528,500
Analysis of Coronavirus-Host Cell Interactions						
3 <a href="#">R01AI099107-03S1</a>	 <a href="#">MAKINO, SHINJI</a> 	UNIVERSITY OF TEXAS MED BR GALVESTON	2014	NIAID	NIAID	\$30,327
RBD recombinant protein-based SARS vaccine for biodefense						
3 <a href="#">R01AI098775-03S1</a>	 <a href="#">HOTEZ, PETER J</a>  <a href="#">BOTTAZZI, MARIA ELENA</a>  <a href="#">JIANG, SHIBO</a> 	BAYLOR COLLEGE OF MEDICINE	2014	NIAID	NIAID	\$3,936
Deciphering the Role of the Coronavirus Macro Domain in SARS-CoV Infection						
1 <a href="#">F32AI113973-01</a>	 <a href="#">FEHR, ANTHONY R</a> 	UNIVERSITY OF IOWA	2014	NIAID	NIAID	\$53,282



**Martin Friede, Ph.D.**

Coordinator, Initiative for Vaccine Research at the World Health Organization  
(mSAC Chair)



**Dr. Danilo Casimiro, Ph.D.**

Chief Science Officer & Global Head, External Scientific Affairs, Sanofi Vaccines



**Barney Graham, M.D., Ph.D.**

Former Deputy Director of the Vaccine Research Center at the National Institutes of Health and the Chief of the Viral Pathogenesis Laboratory.



**Drew Weissman, M.D., Ph.D.**

MD, PhD, Co-Director, Penn Center for AIDS Research, Immunology Core, Director of Vaccine Research, Infectious Diseases Division



**Duccio Medini, Ph.D.**

R3 Program Director at Wellcome Leap, global ARPA for Health, and Strategic Data Science Director at Toscana Life Sciences Foundation, Siena (Italy).



**Dr. Connie Schmaljohn**

Director, NIAID Integrated Research Facility (IRF-Frederick)



**Suhaib Siddiqui, Ph.D.**

Former director of chemistry at Moderna Founder of Antima Inc



**Kiat Ruxrungtham, M.D.**

Professor of Medicine, Department of Medicine Chulalongkorn University; and Scientific Chair of the Chula Vaccine Research Center

**USAMRIID/IRF  
at NIH,  
Awarded by  
the US ARMY**

**Director at Moderna**

**Vanderbilt  
NIH's VRC**

**UPenn  
Nobel Winner for  
mRNA**

<https://medicinespatentpool.org/who-we-are/governance-teams#Advisory-Panels/>



[Integrated Research Facility at Fort Detrick](#)
[About the IRF-Frederick](#)
[Leadership and Scientists](#)
[How To Work With the IRF-Frederick](#)

Research > [Integrated Research Facility at Fort Detrick](#)

## Integrated Research Facility Leadership and Scientists

### IRF-Frederick Leadership

<https://www.niaid.nih.gov/research/integrated-research-facility-leadership-scientists>

#### Connie Schmaljohn, Ph.D.

Director, Integrated Research Facility at Fort Detrick  
Contracting Officer's Representative (COR)

**Contact:** [For contact information, search the NIH Enterprise Directory.](#)

Dr. Connie Schmaljohn was selected and became Director, IRF-Frederick in November 2019. Prior to that time, she was Senior Research Scientist for Medical Defenses Against Infectious Disease Threats and directed a research program at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Dr. Schmaljohn earned a B.S. degree in microbiology from the University of Nebraska and a...



### Biography

Dr. Connie Schmaljohn was selected and became Director, IRF-Frederick in November 2019. Prior to that time, she was Senior Research Scientist for Medical Defenses Against Infectious Disease Threats and directed a research program at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

Dr. Schmaljohn earned a B.S. degree in microbiology from the University of Nebraska and a Ph.D. in virology from Colorado State University, after which she joined USAMRIID as a National Research Council postdoctoral fellow. Her subsequent positions at USAMRIID included Principal Investigator as well as Chief, Molecular Virology Branch. Dr. Schmaljohn's research background is in molecular virology and molecular vaccine development. She has served as president of the International Society of Hantaviruses, chair of the American Society for Microbiology Biodefense Conference, and chair of the International Committee on the Taxonomy of Viruses *Bunyaviridae* Study Group. She also has served on the Interagency Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Viral Hemorrhagic Fevers Integrated Product Team (IPT), the Board of Scientific Counselors for the NIAID Vaccine Research Center, and the Scientific Advisory Council for the Coalition of Emergency Preparedness Innovations (CEPI). She was elected to the American Academy of Microbiology (2007) and was selected as fellow of the International Society for Vaccines (2015). She received the Order of Military Merit (2002), the Association of Military Surgeons of the United States Research Award (2002), the University of Nebraska Alumni Achievement Award (2012), and the Presidential Rank Award (2017).



Dr. Connie S. Schmaljohn of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has been awarded the Meritorious Senior Professional Rank Award for the Department of the Army for 2017.

Schmaljohn is Senior Research Scientist for Medical Defense Against Infectious Disease Threats (ST) at USAMRIID and her research involves developing medical countermeasures against highly lethal viruses of military importance. She was instrumental in the discovery of hantaviruses, a previously unknown class of rodent-borne viruses that cause hemorrhagic fever or severe respiratory

[https://www.army.mil/article/210940/usamriids\\_schmaljohn\\_receives\\_presidential\\_rank\\_award](https://www.army.mil/article/210940/usamriids_schmaljohn_receives_presidential_rank_award)

## Therapure Biomanufacturing Signs Manufacturing Deal With VBI Vaccines for Coronavirus Vaccine Candidates

August 18, 2020 09:04 AM Eastern Daylight Time

MISSISSAUGA, Ontario--([BUSINESS WIRE](#))--Therapure Biomanufacturing, a division of Therapure Biopharma Inc., announced today the signing of an agreement with VBI Vaccines Inc. for the manufacture of their coronavirus vaccine candidates. Therapure Biomanufacturing is an integrated contract development and manufacturing organization (CDMO) focused on biologic and high value therapeutics that can provide new options for patient care. Under this agreement, Therapure will be responsible for the biomanufacturing of the vaccine drug substance as well as the aseptic fill of the drug product at the Therapure facility in Mississauga, Ontario.

Mr. Safa'a Al-Rais, Therapure's Chief Operating Officer, said: "We are delighted to partner with VBI to assist with providing an effective response to the ongoing COVID-19 pandemic through Therapure's biomanufacturing and aseptic fill finish services for VBI's innovative COVID-19 vaccine candidates, which utilize their flexible enveloped virus-like particle (eVLP) platform technology. Therapure prides itself on its development, clinical and commercial cGMP manufacturing expertise providing solutions for biologic therapeutics and innovative drug delivery technologies, which make a difference in patients' lives."

"We look forward to working with Therapure to address the ongoing public health challenge," said Jeff Baxter, VBI's President and CEO. "Therapure's proven cGMP biomanufacturing capabilities and expertise with aseptic fill finish make them a great partner as we advance our vaccine candidate into and through clinical studies."

### [ABOUT THERAPURE BIOMANUFACTURING](#)

Therapure Biomanufacturing is the award-winning contract development and manufacturing division of Therapure Biopharma Inc. offering integrated services for developing, manufacturing, purifying and packaging complex biological therapeutics and technologies. Our scientific and manufacturing expertise, as well as our flexible state-of-the-art facility with a successful regulatory track record including an FDA approval for commercial manufacturing, provides clients with optimal biomanufacturing solutions to advance their

**<https://www.businesswire.com/news/home/20200818005214/en/Therapure-Biomanufacturing-Signs-Manufacturing-Deal-VBI-Vaccines>**





Coronavirus

Press Releases

# CEPI and VBI Vaccines Collaborate to Advance Vaccine Candidates Against COVID-19 Variants

March 10, 2021

- *Up to \$33m of funding will support development of VBI's enveloped virus-like particle (eVLP) vaccine candidates against COVID-19 variants of concern.*
- *Phase 1 clinical study of VBI's eVLP vaccine candidate, VBI-2905, targeting the B.1.351 variant, anticipated to initiate mid-year 2021.*

CEPI, the Coalition for Epidemic Preparedness Innovations, and VBI Vaccines Inc. ([Nasdaq: VBIV](#)), today announced a partnership to



# Commercial Advisory Board

[Management Team](#)[Board of Directors](#)[Scientific and Clinical Advisory Boards](#)[Commercial Advisory Board](#)

## Meet Our Commercial Advisors

This Board, comprised of public health policy, epidemiology, and vaccine development experts, works closely with our management team to provide guidance for the pre-launch and commercialization strategy of our pipeline programs.

---

### **Damian Braga**

Director, Chair of Commercial Advisory  
Board

### United States

**Eddy A. Bresnitz, M.D., M.S.C.E.**

**Michael D. Decker, M.D., M.P.H.**

**John D. Grabenstein, Ph.D., R.Ph.**

Eddy A. Breshniz, M.D., M.S.C.E.

Michael D. Decker, M.D., M.P.H.

John D. Grabenstein, Ph.D., M.P.H.

< Sanofi, CDC, Vanderbilt

## Michael D. Decker, M.D., M.P.H.

Current Adjunct Professor of Preventive Medicine at Vanderbilt University Medical Center, Dr. Decker is a well-published expert on vaccines, preventive medicine, and public health policy. In 2016, Dr. Decker retired from Sanofi Pasteur after more than 15 years, where he was Vice President and Global Medical Expert from 2013–2016 and Vice President, Scientific and Medical Affairs, and Chief Medical Officer, Sanofi Pasteur U.S., from 2000–2012. From 1984–2000, Dr. Decker was a Professor of Preventive Medicine and Medicine (Infectious Diseases) at Vanderbilt University School of Medicine. He has also previously served as a Medical Officer in the U.S. Public Health Service at the Centers for Disease Control and Prevention (CDC), as Editor-in-Chief of the journal Infection Control and Hospital Epidemiology from 1993 to 2001, and as Co-Editor of the International Journal of Health Governance from 2016 to 2020.



## David E. Anderson, Ph.D.

### Chief Scientific Officer

A dynamic and well-published immunologist with broad expertise in the areas of vaccine development, autoimmunity and tumor immunology, Dr. Anderson joined VBI full time in 2009 from Harvard Medical School, where he held a position as Assistant Professor. As a co-founder and Chief Scientific Officer of VBI, Dr. Anderson is an inventor of much of the Company's intellectual property and actively manages its ongoing expansion. Dr. Anderson holds a Ph.D. from Harvard University and a B.S. from the University of California at Davis.

Harvard + UC Davis>





# Scientific and Clinical Advisory Boards

[Management Team](#)[Board of Directors](#)[Scientific and Clinical Advisory Boards](#)[Commercial Advisory Board](#)

## Meet Our Scientific and Clinical Advisors

These highly-regarded global experts in infectious disease, immuno-oncology, and vaccine development help guide the advancement and direction of our pipeline programs.

**Michel De Wilde, Ph.D.**

Director, Chair of Scientific and Clinical Advisory  
Boards

### Hepatitis B Virus (HBV)

**Adam Finn, M.D., Ph.D.**

**Peter A. Patriarca, M.D.**

**Daniel Shouval, M.D.**

**Bruce Smith, Ph.D.**

**Stefan Thoelen, M.D.**

**Pierre Van Damme, M.D., Ph.D.**

### Glioblastoma (GBM)

**Denis R. Burger, Ph.D.**

**Michael Lim, M.D.**

**Allen Waziri, M.D.**

**Patrick Yung Wen, M.D.**

### Cytomegalovirus (CMV)

**Robert Pass, M.D.**

**Stanley Plotkin, M.D.**



## John D. Grabenstein, Ph.D., R.Ph.

Dr. Grabenstein is a global vaccinologist, pharmacist, epidemiologist, and public-health leader specializing in adult vaccines, implementation, and vaccine history. Currently, Dr. Grabenstein is president of consulting service Vaccine Dynamics SP, and is also Associate Director of Scientific Communications for the Immunization Action Coalition (IAC), a non-profit organization working to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public. Previously, he spent over 13 years at Merck Vaccines, most recently serving as Global Executive Director of Medical Affairs until his retirement in late 2019. Before joining Merck, Dr. Grabenstein served for 27 years in the U.S. Army Medical Department, achieving the rank of Colonel. From 1999 to 2006, he directed the scientific elements of the U.S. Department of Defense (DoD) anthrax and smallpox vaccination programs. As Director, Military Vaccine Agency, he was responsible for science, communication, education, and safety surveillance of military immunizations for 2.6 million U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard personnel deployed globally.

### Navigate

- About Us
- Our Focus
- Our Science & Technology
- Our Pipeline
- Clinical Trials
- Investors
- Contact Us

# Steven Gillis, Ph.D.

## Chairman of the Board

Steven Gillis, Ph.D., has been a Managing Director of ARCH Venture Partners since 2006 and joined the firm in 2005. Dr. Gillis is focused on the evaluation of new life science technologies and also on the development and growth of ARCH's biotechnology portfolio companies. He is a director of Takeda Pharmaceutical Co. Ltd. (TAK), Homology Medicines, Inc. (FIXX), and also serves as Chairman of Codiak Biosciences (CDAK). Dr. Gillis represents ARCH as a managing director and serves as Chairman of a number of ARCH's private, biotechnology portfolio companies.

Dr. Gillis was a founder and director of Corixa Corporation and served as CEO from its inception and as its Chairman from 1999 until its acquisition in 2005 by GlaxoSmithKline. Prior to Corixa, Dr. Gillis was a founder and director of Immunex Corp. From 1981 until his departure in 1994, Dr. Gillis served as Immunex's Director of Research and Development, Chief Scientific Officer, and as CEO of Immunex's R&D subsidiary. Dr. Gillis was interim CEO of Immunex Corp. following its majority purchase by American Cyanamid Company and remained a member of the board until 1997. Amgen, Inc. acquired Immunex in 2002.

Dr. Gillis is an immunologist by training with over 300 peer-reviewed publications in the areas of molecular and tumor immunology. He is credited as being a pioneer in the field of cytokines and cytokine receptors, directing the development of multiple marketed products including Leukine, (GM-CSF), Prokine (IL-2) and Enbrel (soluble TNF receptor-Fc fusion protein) as well as the regulatory approval of Bexxar (radiolabeled anti-CD20). Dr. Gillis received a B.A. from Williams College and a Ph.D. from Dartmouth College.

**< ARCH VENTURES**  
**Takeda**  
**GSK**  
**Immunex**  
**[prior to acquisition by Amgen,]**  
**DARTMOUTH**



# Michel De Wilde, Ph.D.

## Director



Michel De Wilde, Ph.D., was Senior Vice President, Research & Development, at Sanofi Pasteur, the human vaccines division of Sanofi from 2001 until June 2013. In this position, he was responsible for managing approximately 1,500 employees and a broad portfolio of approximately 20 development projects.

Prior to joining Sanofi Pasteur in January 2000, Dr. De Wilde was at SmithKline Beecham Biologicals (now GSK Vaccines) in Rixensart, Belgium. Dr. De Wilde joined the group in 1978 as a research scientist upon formation of a unit focusing on the application of recombinant DNA technology to vaccine development. He subsequently held positions of increasing responsibility and, as Vice President, Research & Development at Sanofi Pasteur, headed a team of approximately 400 specialists, active in all aspects of preclinical vaccine development.

Dr. De Wilde a member of a number of Scientific Advisory Boards, including COVAX Independent Product Group and other COVID related advisory bodies.

Dr. De Wilde received his degree in Chemistry from the Free University of Brussels in 1971, followed by a Ph.D. in Biochemistry in 1976. He carried out postdoctoral work at the University of Wisconsin, Madison (U.S.) and the University of Ghent (Belgium). Dr. De Wilde authored over 50 publications during the early part of his career.

**^Sanofi, GSK, COVAX, University of Wisconsin Madison**



## John D. Grabenstein, Ph.D., R.Ph.

Dr. Grabenstein is a global vaccinologist, pharmacist, epidemiologist, and public-health leader specializing in adult vaccines, implementation, and vaccine history. Currently, Dr. Grabenstein is president of consulting service Vaccine Dynamics SP, and is also Associate Director of Scientific Communications for the Immunization Action Coalition (IAC), a non-profit organization working to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public. Previously, he spent over 13 years at Merck Vaccines, most recently serving as Global Executive Director of Medical Affairs until his retirement in late 2019. Before joining Merck, Dr. Grabenstein served for 27 years in the U.S. Army Medical Department, achieving the rank of Colonel. From 1999 to 2006, he directed the scientific elements of the U.S. Department of Defense (DoD) anthrax and smallpox vaccination programs. As Director, Military Vaccine Agency, he was responsible for science, communication, education, and safety surveillance of military immunizations for 2.6 million U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard personnel deployed globally.

### Navigate

[About Us](#)

[Our Focus](#)

[Our Science & Technology](#)

[Our Pipeline](#)

[Clinical Trials](#)

[Investors](#)

[Contact Us](#)

## Our Partnerships and Collaborations



**Brii Biosciences (Brii Bio)**

VBI and Brii Bio have a license and collaboration agreement for the development of VBI-2601 (BRII-179) as part of a potential functional cure for chronic hepatitis B infection.

[Read Press Release](#) ➤

**Government of Canada**

Through their Strategic Innovation Fund, the Government of Canada awarded VBI up to a CAD \$56 million contribution to support the development of the Company's prophylactic coronavirus vaccine candidates, VBI-2901 and VBI-2902, through Phase 2 clinical studies.



**Coalition for Epidemic Preparedness Innovations (CEPI)**

As part of their collaboration, CEPI will provide VBI up to \$33M of funding to support development of VBI's eVLP vaccine candidates against COVID-19 variants of concern, including B.1.351, the variant first identified in South Africa.

[Read Press Release](#) ➤

**GlaxoSmithKline (GSK)**

VBI and GSK have a collaboration to clinically evaluate the combination of VBI-1901, VBI's cancer vaccine immunotherapeutic candidate, with GSK's proprietary AS01 adjuvant system in patients with recurrent glioblastoma (GBM).

[Read Press Release](#) ➤**Resilience Biotechnologies, Inc. (Resilience)**

(previously Therapure Biopharma Inc.)

VBI and Resilience have an agreement for the development and manufacturing services in preparation for production of its coronavirus vaccine candidates. The collaboration is expected to support clinical studies through Phase 2 clinical development.



### Syneos Health (Syneos)

VBI and Syneos Health have a partnership for commercialization of VBI's prophylactic hepatitis B program.

[Read Press Release](#) ➤





### President (Term: 2022-2024)

**John D. Grabenstein**, RPh, PhD, ScD (Hon), is a globally recognized vaccinologist, pharmacist, and leader. He has authored over 300 articles and 11 books, primarily on topics of immunization, public health, and leadership. He is currently a consultancy providing services related to human vaccines, antibody products, and other immunologic drugs. He also serves as the Managing Editor of *IZ Express*, the newsletter of Immune.org.

Dr. Grabenstein received his pharmacy degree from Duquesne University, a master's degree in education from Boston University, and a doctorate in epidemiology at the University of North Carolina. He was elected to the National Academy of Medicine in 2021 and is a Fellow of the Royal Society for Public Health. Dr. Grabenstein is the 2020 recipient of APhA's Remington Honor Medal, American pharmacy's highest honor for distinguished service. An AIHP member since 1994, Dr. Grabenstein joined the Institute's Board of Directors in 2018, served as Vice President from 2020-21, and became the organization's President in November 2021.

Dr. Grabenstein's prior positions include Global Director of Medical Affairs for Merck Vaccines (where he led medical-affairs and scientific-policy activities for a global enterprise that provided 180 million doses annually for 13 vaccines) and Director of the U.S. Department of Defense's Military Vaccine Agency (where he oversaw the Defense Department immunization programs for 9 million troops, retirees, and family members spread across four continents and dozens of ships at sea).

**From:** Peter Daszak  
**Sent:** Tuesday, April 28, 2020 11:30 AM  
**To:** 'Hongying Li' <li@ecohealthalliance.org>; Tammie O'Rourke <torourke@metabiota.com>  
**Cc:** Goldstein, Tracey <tgoldstein@ucdavis.edu>; Aleksei Chmura <chmura@ecohealthalliance.org>; Christine Kreuder Johnson <ckjohnson@ucdavis.edu>  
**Subject:** RE: China Genbank Sequences  
**Importance:** High

All – It's extremely important that we don't have these sequences as part of our PREDICT release to Genbank at this point.

As you may have heard, these were part of a grant just terminated by NIH.

<https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076>

Having them as part of PREDICT will bring very unwelcome attention to UC Davis, PREDICT and USAID.

Cheers,

Peter

**This email from Daszak was sent out to EHA and Metabiota staff urging them not to publish Viral Sequences to Genbank for fear it would bring “very unwelcome attention to UC Davis, PREDICT and USAID”**

**USAID is a CIA front. The CIA's investment arm, In-Q-Tel is a major funder of Hunter Biden's failed Metabiota.**

**This email occurred 3 weeks BEFORE EHA & Wuhan decided to upload SHC014 [Close chimeric relative to SARS2] to Genbank after 5 years! [May 22 2020]**

This Science News Wire page contains a press release issued by an organization and is provided to you **"as is"** with little or no review from Science X staff.

## Dana-Farber receive \$5.6 million grant to develop rapid countermeasures to infectious agents

January 18th, 2011



BOSTON--Researchers at Dana-Farber Cancer Institute have received a \$5.6 million grant from the Defense Advanced Research Projects Agency (DARPA) and the Army Research Office (ARO) to develop transient immunity against known, unknown, naturally occurring, or engineered disease-causing pathogens. The ultimate goal is to develop a viable countermeasure to an unknown pathogen within seven days of receiving it in a laboratory.

## Wayne Marasco of the NIH's Vaccine Research Center working with in 2011 DARPA for;

***"This grant will support revolutionary advances in rapid response to naturally evolving AND ENGINEERED PATHOGENS."***

BOSTON--Researchers at Dana-Farber Cancer Institute have received a \$5.6 million grant from the Defense Advanced Research Projects Agency (DARPA) and the Army Research Office (ARO) to develop transient immunity against known, unknown, naturally occurring, or engineered disease-causing pathogens. The ultimate goal is to develop a viable countermeasure to an unknown pathogen within seven days of receiving it in a laboratory.

Wayne A. Marasco, MD, PhD, of the Department of Cancer Immunology and AIDS at Dana-Farber and an associate professor of Medicine at Harvard Medical School, is the project's principal investigator.

Since the mid 1990's, DARPA's Defense Sciences Office has pioneered advances across the full spectrum of bio-warfare defense needs, including the development of advanced diagnostics and medical therapies that are active against an entire range of infectious agents.

"This grant will support revolutionary advances in rapid response to naturally evolving and engineered pathogens," says Marasco. "DARPA has issued a challenge to develop a treatment to unknown threats in just seven days, and we are excited about the opportunity to meet this challenge."





Journal of Immunological Methods 246 (2000) 97–108

**JIM**  
Journal of  
Immunological Methods

[www.elsevier.nl/locate/jim](http://www.elsevier.nl/locate/jim)

# Expression of a human, neutralizing monoclonal antibody specific to Puumala virus G2-protein in stably-transformed insect cells

Mary C. Guttieri\*, Carol Bookwalter, Connie Schmaljohn

*Virology Division, United States Army Medical Research Institute of Infectious Diseases, Bldg. 1301, Fort Detrick, Frederick, MD 21702-5011, USA*

Received 29 May 2000; received in revised form 12 September 2000; accepted 13 September 2000

Strange how **Metabiota's Guttieri** collaborated with USAMRIID/IRFs  
**Schmaljohn on Monoclonal Antibodies at Fort Detrick in 2000**

<https://www.uvm.edu/~cbookwal/296c/guttieri.pdf>

## Therapure Biopharma Awarded US Government Contract

**News** Published: June 20, 2013

Therapure Biopharma Inc. has announced the company will participate as a subcontractor for DynPort Vaccine Company LLC (DVC), a CSC company, that was awarded a US cost-plus-fixed-fee contract with a maximum value of \$157.3 million (prime contract number W911QY-13-C-0056) by the US Department of Defense (DoD) to support the development of a prophylactic countermeasure to prevent the effects of organophosphorus nerve agent poisoning.

## Therapure Biopharma

### Therapure Biopharma Awarded US Government Contract for Development of Anti-Nerve Gas Agent

Make an enquiry

Therapure Biopharma, a contract development and manufacturing organization (CDMO) of biotherapeutics, is pleased to announce that the company will participate as a subcontractor for DynPort Vaccine Company (DVC), a CSC company, that was awarded a US cost-plus-fixed-fee contract with a maximum value of \$157.3m (prime contract number W911QY-13-C-0056) by the US Department of Defense (DoD) to support the development of a prophylactic countermeasure to prevent the effects of organophosphorus nerve agent poisoning.

Therapure's subcontract under the above prime contract includes process optimization as well as manufacture of all clinical and nonclinical materials (drug product) to support DVC's contract to develop, test and obtain the US Food and Drug Administration (FDA) approval for human plasma-derived butyrylcholinesterase (HuBChE), a blood plasma protein that binds and inactivates nerve agents. Mr Nick Green, therapure's president and chief executive officer, said; "We are delighted to partner with DVC to develop and manufacture medical counter measures for the US Department of Defense as part of a defense strategy against a wide range of nerve gases. Therapure successfully completed a rigorous selection and approval process to serve as the manufacturing subcontractor under the prime contract, which is a testament to the company's standards and capabilities in biomanufacturing. It is an honor to be part of this very critical initiative to protect US Servicemen and women."

Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the US Department of Defense, Department of the Army, Chemical Biological Medical Systems Joint Project Management Office (CBMS JPMO), Medical Identification and Treatment Systems Joint Product Management Office (MITS JPMO).

<https://www.pharmaceutical-technology.com/contractors/contract-manufacturers/therapure-biopharma/pressreleases/presstherapure-biopharma-awarded-us-government-contract-for-development-of-anti-nerve-gas-agent/>



# RESILIENCE BIOTECHNOLOGIES INC.

**Company Number** BC1259445

**Status** Active

**Incorporation Date** 30 July 2020 (almost 3 years ago)

**Company Type** BC Company

**Jurisdiction** [British Columbia \(Canada\)](#)

**Business Number** 720950070

**Registry Page** <https://www.orgbook.gov.bc.ca/entity/...>

## Latest Events

2020-07-30
[Incorporated](#)

[See all events](#)

## Corporate Grouping USER CONTRIBUTED

None known. [Add one now?](#)

[See all corporate groupings](#)

## Recent filings for RESILIENCE BIOTECHNOLOGIES INC.

1 Oct 2020 [NOTICE OF ALTERATION](#)

Source OrgBook BC, <https://www.orgbook.gov.bc.ca/search>, 1 Jul 2023

**JULY 30 2020**



## Resilience Receives USD \$164 Million Investment from the Government of Canada to Modernize and Expand Its Ontario Biomanufacturing Site, Improving Pandemic Preparedness

 **RESILIENCE**



NATIONAL RESILIENCE, INC.

- **Headquarters:** San Diego, California, US
- **Website:** [www.resilience.com](http://www.resilience.com)
- **CEO:** Rahul Singhvi
- **Employees:** 1,600
- **Organization:** PRI

[Release Summary](#)

Safa'a Al-Rais, Chief Operating Officer at Ontario-based subsidiary Resilience Biotechnologies Inc. (RBI), a subsidiary of National Resilience, Inc. (Resilience), discusses the Canadian Government's CAD 199.2 million (\$163.8 million) investment in the site, through the Strategic Innovation Fund. The investment will help increase manufacturing capacity for vaccines and therapeutics, including novel technologies such as mRNA that are being used to fight COVID-19. The expansion will build on RBI's existing strengths as an important biomanufacturing organization in Canada, maintaining 295 existing jobs and create 205 new full-time positions at the Mississauga facility.



May 18, 2021 12:15 PM Eastern Daylight Time

SAN DIEGO & BOSTON--(BUSINESS WIRE)--National Resilience, Inc. (Resilience), a company building the world's most advanced biopharmaceutical manufacturing ecosystem, announced that the Government of Canada will invest CAD 199.2 million (\$163.8 million), through the [Strategic Innovation Fund](#), in the company's Ontario-based subsidiary Resilience Biotechnologies Inc. (RBI) to modernize and expand production capacity.

**"Resilience was founded during the pandemic to build a better system for manufacturing complex medicines to fight deadly diseases"**

 [Tweet this](#)

This project will help increase manufacturing capacity for vaccines and therapeutics, including novel technologies such as mRNA that are now being used to fight COVID-19. The expansion will build on RBI's existing strengths as an important biomanufacturing organization in Canada, maintaining 295 existing jobs and create 205 new full-time positions at the Mississauga facility.

"Resilience was founded during the pandemic to build a better system for manufacturing complex medicines to fight deadly diseases," said Rahul Singhvi, Sc.D, Chief Executive Officer of Resilience. "This partnership with the Government of Canada will help prepare Canada for future pandemics and strengthen the country's biopharmaceutical ecosystem."

"The Government of Canada's top priority is to protect the health and safety of Canadians. Today's contribution to Resilience Biotechnologies Inc. is another important step to support Canada's leadership in the life sciences sector and to build future pandemic preparedness. These investments are also creating well-paying jobs and helping to grow Canada's life sciences ecosystem as an engine

**MAY 18 2021**

**RESILIENCE BIOTECHNOLOGIES  
INC IS THE ONTARIO BASED  
SUBSIDIARY OF NATIONAL  
RESILIENCE INC**

**THE GOVERNMENT OF  
CANADA INVESTED  
\$163.8M**



# Resilience (Durham)

National Resilience manufactures viral vectors, a component of cell and gene therapies.

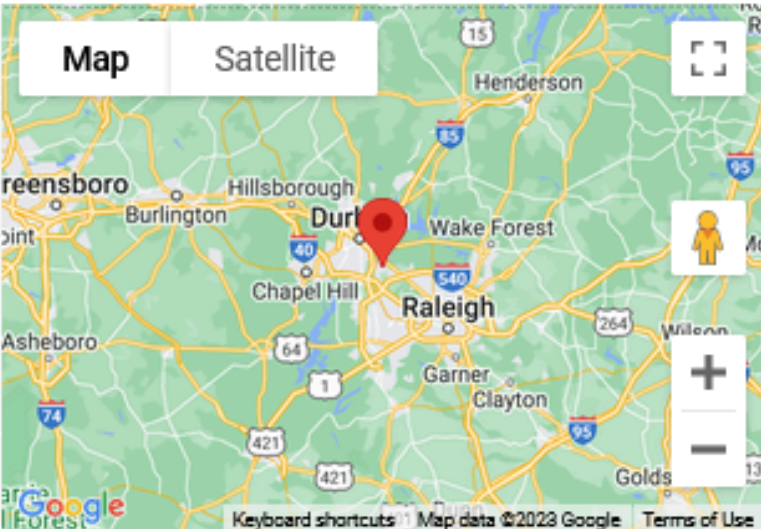
<https://resilience.com>

1733 T.W. Alexander Drive  
Durham NC 27703

Phone (984) 202-0854

County Durham

Region Triangle



## Company Details

Company type Bioscience Company	Year founded 2020
Employment range in NC 100-199	US headquarters California
Global headquarters United States	Primary site activity Production and Manufacturing
All company activities Production and Manufacturing	Core capabilities Gene Therapy Formulation or Fill and Finish
Potential end market(s) Therapeutics - Gene- and Cell-based Therapies Therapeutics - Large Molecule (biologics) Cancers and other Neoplasms Congenital and Genetic Diseases	

<https://bioprocessintl.com> > bioprocess-insider > canada-pays-164-million-to-add-resilience  
Canada adds Resilience to pandemic prep for \$164 - BioProcess .

Canada has called on Resilience Biotechnologies to boost local COVID-19 shot capacity. The Canadian Government has given contract development manufacturing organization (CDMO) Resilience Biotechnologies \$164 million to modernize its recently acquired Ontario plant as part of a wider pandemic preparedness effort.

<https://directory.ncbiotech.org> > company > resilience-durham  
Resilience (Durham) | North Carolina Biotech Center

National Resilience manufactures viral vectors, a component of cell and gene therapies.

<https://www.lobbycanada.gc.ca> > app > secure > ocl > lrs > do > vwRg?cno=368948  
Registration - In-house Corporation - Commissioner of Lobbying ..

In-house Corporation Details Description of activities Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics.

<https://www.theofficialboard.com> > news > resilience-biotechnologies  
News at Resilience Biotechnologies - The Official Board

Jun 8, 2022 · Resilience Biotechnologies has 2,177 competitors including Eurofins (Luxembourg)



A public directory of organizations registered in BC

RESILIENCE BIOTECHNOLOGIES INC.



[How to search?](#)

[Filters](#)

114 result(s)

**RESILIENCE BIOTECHNOLOGIES INC.**

BC Company  
Business number: 720950070  
Incorporation number: BC1259445



[← Back to search](#)

**RESILIENCE BIOTECHNOLOGIES INC.**

Business number: 720950070  
Active • BC Company

ACTIVE

[Registration](#) [Relationships](#) [Qualifications](#)

[Show all Credential statuses](#)

**Registration**

RESILIENCE BIOTECHNOLOGIES INC. is a [BC Company](#)

Incorporation number: BC1259445  
Registered on: Jul 29, 2020  
Business name effective: Jul 29, 2020

# Registration - In-house Corporation

[Share this page](#)

## Resilience Biotechnologies, Inc. / Sankalp Vashishtha, Vice President / General Manager

### Registration Information

In-house Corporation name: **Resilience Biotechnologies, Inc.**  
Responsible Officer Name: **Sankalp Vashishtha, Vice President / General Manager**   
[Responsible Officer Change History](#)  
Initial registration start date: **2021-02-24**  
Registration status: **Active**  
Registration Number: **953057-368948**

### Associated Communications

Total Number of Communication Reports: **0**  
Monthly communication reports in the last 6 months: **0**

« < Registration versions: 5 of 5: 2023-02-20 to present ▾

### Version 5 of 5 (2023-02-20 to present)

#### Lobbying Information

#### In-house Corporation Details

#### Lobbyists Details

#### Description of activities

Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario-based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics. RBI's mission is to support for Canadian vaccine and therapeutics production and serve as a long-term partner for Canadian pharmaceutical manufacturing.

#### Responsible officer name and position during the period of this registration

Sankalp Vashishtha, Vice President / General Manager



**Description of activities**

Resilience Biotechnologies (RBI), formerly Therapure Biopharma, is a wholly owned subsidiary of National Resilience, Inc. RBI is an Ontario-based Contract Development and Manufacturing Organization (CDMO) specializing in the development and manufacturing of complex biologics. RBI’s mission is to support for Canadian vaccine and therapeutics production and serve as a long-term partner for Canadian pharmaceutical manufacturing.

**Responsible officer name and position during the period of this registration**

Sankalp Vashishtha, Chief Operating Officer, interim

**Government funding**

End date of the last completed financial year: 2021-12-31

Government Institution	Funding Received in Last Financial Year	Funding Expected in Current Financial Year
National Research Council (NRC)	\$2,063,196.23	Yes

**In-house Corporation Contact Information**

Address:2585 Meadowpine Blvd.  
Mississauga, ON L5N 8H9  
Canada

Telephone number: 905-286-6200

**Parent Company Information**

- National Resilience, Inc.
  - 9310 Athena Circle, Suite 130  
La Jolla, CA 92037  
United States of America

**Subsidiary Beneficiary Information**

Resilience Biotechnologies, Inc. does not have any subsidiaries that could have a direct interest in the outcome of the undertaking



ORGANIZATION

# Therapure Biopharma

CONNECT TO CRM

SAVE



Summary

People

Technology

Signals &amp; News

Similar C



## About

Therapure is an integrated Contract Development and Manufacturing Organization.

Acquired by



3SBio Inc.



Mississauga



251-500



Private



www.therapurebio.com/

## Highlights

Contacts

54

Employee  
Profiles

1

Similar  
Companies

3



## Recent News & Activity

News • Aug 11, 2020

PharmiWeb.com — Global Artificial Blood Substitutes Market

Acquisition • Sep 3, 2017

3SBio Inc. acquired Therapure Biopharma for \$290,000,000

[Discover more acquisitions](#)

## Details

Industries

Manufacturing

Founded Date

2008

Operating Status

Active

Company Type

For Profit

Contact Email

info@therapurebio.com

Phone Number

1(905)286-6200

At Therapure Biopharma Inc. they're specialists in biologics therapeutics, and they act on a passion for enhancing patient care through their three divisions: Therapure Biomanufacturing, Therapure Innovations and Therapure Biologics.



## Recent News & Activity

Number of Articles

1

News • Aug 11, 2020

PharmiWeb.com — Global Artificial Blood Substitutes Market

Acquisition • Sep 3, 2017

3SBio Inc. acquired Therapure Biopharma for \$290,000,000

[Discover more acquisitions](#)

## M&A Details

Therapure Biopharma was acquired by 3SBio Inc. for \$290M on Sep 3, 2017.

Transaction Name



Therapure Biopharma acquired by ...

Acquired by



3SBio Inc.

Announced Date

Sep 3, 2017

Price

\$290M



Details

Industries

Biotechnology

Founded Date  
1993

Operating Status  
Active

Legal Name  
Sunshine Guojian Pharmaceuticals  
(Shanghai) Co., Ltd.

Stock Symbol  
NASDAQ:SSRX

Number of Exits  
1

Phone Number  
+862425386000

3SBio is a fully integrated, profitable biotechnology company focused on researching, developing, manufacturing and marketing biopharmaceutical products primarily in China. Its focus is on addressing large markets with significant unmet medical needs in nephrology, oncology, supportive cancer care, inflammation and infectious diseases. With headquarters and GMP-certified manufacturing facilities in Shenyang, PRC, 3SBio employs over 800 people.

Headquarters Regions  
Asia-Pacific (APAC)

Founders  
Dr. Jing Lou

Last Funding Type  
Post-IPO Equity

Company Type  
For Profit

Frequently Asked Questions



Where is 3SBio Inc.'s headquarters? 3SBio Inc. is located in **Shenyang, Liaoning, China**.

Who invested in 3SBio Inc.? 3SBio Inc. is funded by **Numab**.

How much funding has 3SBio Inc. raised to date? 3SBio Inc. has raised **CHF15M**.

When was the last funding round for 3SBio Inc.? 3SBio Inc. closed its last funding round on **Dec 12, 2019** from a **Post-IPO Equity** round.

Who are 3SBio Inc.'s competitors? Alternatives and possible competitors to 3SBio Inc. may include **Brainsway, Innovative Cellular Therapeutics, and MabSpace Biosciences**.



# Resilience Biotechnologies Inc.

★★★★★  
( 0 Reviews )

📍 1733 TW Alexander Dr  
Durham, NC 27703

Header	Company	Date ▼	News Type
<a href="#">Proposed Initial Public Offering</a>			
<a href="#">Therapure Biopharma Launches Biologics Division as Evolve Biologics, an Innovative Plasma-Derived Therapeutics Company</a>	Evolve Biologics Inc. Resilience Biotechnologies Inc.	2018-03-23	Financial News
<a href="#">Therapure Biopharma Inc. Wins the Mississauga Board of Trade's 2017 Business Awards of Excellence</a>	Resilience Biotechnologies Inc.	2017-11-17	Other Company News
<a href="#">Therapure Biopharma Inc. Ranks No. 115 on the 2017 PROFIT 500 – Its 4th Consecutive Year on the List</a>	Resilience Biotechnologies Inc.	2017-09-27	Other Company News
<a href="#">3SBio Accelerates Expansion of Its Global Biologics Platform by Acquiring the Canadian Biomanufacturing Business of Therapure</a>	3SBio Inc. CPE Funds Resilience Biotechnologies Inc.	2017-09-03	Financial News
<a href="#">Therapure Biomanufacturing Receives 2017 CMO Leadership Individual Attribute Awards for Capabilities and Staff Characteristics</a>	Resilience Biotechnologies Inc.	2017-04-05	Other Company News
<a href="#">For a Third Consecutive Year Therapure Biopharma Inc. Ranks in the PROFIT 500 List of the Fastest-Growing Companies in Canada and Ranks 10th in the GTA Manufacturing Sector</a>	Resilience Biotechnologies Inc.	2016-09-30	Other Company News

## Company News



Company Resilience Biotechnologies Inc. ✕

### Company News

Header	Company	Date ▼	News Type
<a href="#">U of T Home to New Hub That Will Strengthen Canada's Pandemic Preparedness and Increase Biomanufacturing Capacity</a>	Centre for Commercialization of Regenerative Medicine adMare BioInnovations CoVaRR-Net Cyclica Inc. Cytiva National Research Council Canada Providence Therapeutics Holdings Inc. Resilience Biotechnologies Inc. Sanofi SA Sartorius Stedim Biotech S.A. University of Saskatchewan University of Toronto	2023-03-02	Financial News
<a href="#">Evolve Biologics Announces Site Selection, Land Purchase and Groundbreaking Ceremony for First Manufacturing Facility in Sachse, Texas</a>	Evolve Biologics Inc. National Resilience, Inc. Resilience Biotechnologies Inc.	2021-12-06	Product News
<a href="#">Resilience Receives USD \$164 Million Investment From the Government of Canada to Modernize and Expand Its Ontario Biomanufacturing Site, Improving Pandemic Preparedness</a>	National Resilience, Inc. Resilience Biotechnologies Inc. Strategic Innovation Fund (SIF)	2021-05-18	Financial News
<a href="#">Evolve Biologics Confirms Selection of DDR</a>			

# RESILIENCE GOVERNMENT SERVICES, INC

BRANCH

**Company Number** F16440265

**Status** Incorporated

**Incorporation Date** 31 March 2015 (over 8 years ago)

**Company Type** FOREIGN CORPORATION

**Jurisdiction** [Maryland \(US\)](#)

**Branch** Branch of [OLOGY BIOSERVICES, INC.](#) (Delaware (US))

**Registered Address** 13200 NW NANO COURT  
ALACHUA  
32615  
FL  
United States

**Previous Names** NANOTHERAPEUTICS, INC  
OLOGY BIOSERVICES, INC

**Business Classification Text** 03 ORDINARY BUSINESS - STOCK

**Agent Name** CSC-LAWYERS INCORPORATING SERVICE

**Agent Address** CSC-LAWYERS INCORPORATING SERVICE,  
COMPANY, 7 ST. PAUL STREET, SUITE 820,  
BALTIMORE, MD, 21202

**Directors / Officers** [CSC-LAWYERS INCORPORATING SERVICE](#), agent

**Registry Page** <https://egov.maryland.gov/BusinessExp...>

Recent filings for RESILIENCE GOVERNMENT SERVICES, INC

## Latest Events

- 2022-05-01 - 2022-05-31

Change of name from 'OLOGY BIOSERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC.'
- 2022-09-01 - 2022-09-30

Change of name from 'RESILIENCE GOVERNMENT SERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC'
- 2022-09-01 - 2022-09-30

Change of name from 'RESILIENCE GOVERNMENT SERVICES, INC.' to 'RESILIENCE GOVERNMENT SERVICES, INC'

[See all events](#)


## Corporate Grouping

USER CONTRIBUTED

None known. [Add one now?](#)

[See all corporate groupings](#)

## Similarly named companies

 [branch](#) **RESILIENCE GOVERNMENT SERVICES, INC.** (Florida (US), 19 Jun 2009- )

 [branch](#) **RESILIENCE GOVERNMENT SERVICES, INC.** (California (US), 22 Mar 2017- )

# Links:

<https://www.theofficialboard.com/org-chart/resilience-biotechnologies>



Resilience Biotechnologies

[www.resilience.com](http://www.resilience.com)



has 25 executives



+1 314 527 0579



Resilience Biotechnologies News



Anything missing? We search for you.



Print or download

Add an executive >

## Board

### CEO & Director

[Rahul Singhvi](#)

### Chairman of the Board

[Robert Nelsen](#)

### Vice Chairman of the Board

[Patrick Yang](#)

### Director

[Frances Arnold](#)

### Director

[George Barrett](#)

### Director

[Mitchell Daniels](#)

### Director

[Chris Darby](#)

## N-1

### CFO & COO

[Sandy Mahatme](#)

### Commercial

[S...](#)

### Digital

[E...](#)

### Legal

[O...](#)

### Manufacturing

[V...](#)

## N-2

### Government & AI Strategy

[O...](#)

### Site Quality

[A...](#)

### Site

[T...](#)



## REPORT TO THE CISA DIRECTOR

Technical Advisory Council

Vulnerability Discovery and Disclosure Recommendations

June 22, 2022

### Introduction:

The Technical Advisory Council Subcommittee was established to leverage the imagination, ingenuity, and technical experts from diverse background and experiences for the good of the nation. The subcommittee is tasked to evaluate and make recommendations tactical and strategic in nature. These Cybersecurity / Critical Incident Response Center (CSAC) recommendations for the June Quarterly Meeting focus on vulnerability discovery and disclosure.

CSAC conducted interviews with sector-specific agencies such as the Food and Drug Administration, vendors, and CISA staff to determine the current state of vulnerability discovery and disclosure process across government and industry and provide meaningful recommendations.



**CISA  
CYBERSECURITY  
ADVISORY  
COMMITTEE**

### Acknowledgements:

#### Technical Advisory Council Members:

Mr. Jeff Moss, Subcommittee Chair, DEF CON Communications

Mr. Dino Dai Zovi, Security Researcher

Mr. Luiz Eduardo, Aruba Threat Labs

Mr. Isiah Jones, National Resilience Inc.

Mr. Kurt Opsahl, Electronic Frontier Foundation

## Former Members of the Board of Directors



**Head of OWS, Moncef Slaoui was also a Board of Directors for Lonza who like Resilience manufactured the Moderna C19 vaccine.**

### Dr Moncef Slaoui

**Independent member of the Board of Directors of Lonza Group Ltd (April 2020 until May 2020)**

Dr Moncef Slaoui brings to Lonza extensive experience from his career with GlaxoSmithKline spanning nearly 30 years. In this time, he held a number of leadership positions, including Member of the Board of GSK PLC, Chairman of Pharmaceutical R&D; and Chairman of Global Vaccines. Currently, Dr Slaoui is partner at Medicxi, a venture capital firm specializing in seed, Series A, early stage and late stage life sciences investments; he also sits on various biotechnology companies' boards. Dr Slaoui received his Ph.D. in Molecular Biology and Immunology from Brussels University in 1983. He later received an accelerated Master of Business Administration from IMD in Lausanne (Switzerland) in 1998.

### Current activities and functions

#### Further Mandates:

- Chairman of Monopteros (A Medicxi Company) (since 2018)
- Chairman of Divide & Conquer (A Medicxi Company) (since 2017)
- Chairman of Sutrovax (since 2017)
- Chairman Galvani Bioelectronics (since 2016)
- Chairman of Clasado (since 2017)

### Activity:

- Partner at Medicxi (since 2017)

### Former activities and functions

- Independent Member of the Board of Directors of Moderna (2017–2020)
- Member of the Advisory Board of the Qatar Foundation (2009–2020)
- Member of the Board of Directors of International AIDS Vaccines Initiatives (2015–2017)
- Member of the Board of GSK PLC (2006–2017)
- Chairman, Global Vaccines of GSK PLC (2009–2017)
- Chairman, Global Research & Development of GSK PLC (2006–2015)
- Various leadership roles in Research & Development including Worldwide Business Development & External Alliances (1988–2003)





Chris Elias

President, Global Development at Bill & Melinda Gates Foundation

## Experience



### President, Global Development

Bill & Melinda Gates Foundation

Feb 2012 - Present · 11 yrs 6 mos

The Bill & Melinda Gates Foundation's Global Development Division works to identify and fund high-impact solutions that can help hundreds of millions of people lift themselves out of ...see more



### President and CEO

PATH

2000 - Jan 2012 · 12 yrs 1 mo

For more than a decade, I served as president and CEO of PATH, an international nonprofit organization dedicated to improving the health of people around the world. At PATH, I ex ...see more



### Senior Associate, International Programs

Population Council

1990 - 2000 · 10 yrs

As a senior associate, I oversaw all Population Council activities in Thailand, Cambodia, Myanmar, Yunnan, and the Lao PDR, encompassing reproductive health programs, interventions resi ...see more

## Interests

Top Voices

Companies

Schools



Peter Sands [in](#) · 3rd

Executive Director at The Global Fund to Fight AIDS, Tuberculosis and Malaria

105,042 followers



Bill Gates [in](#)

Co-chair, Bill & Melinda Gates Foundation

34,786,737 followers



# Christopher Elias

President, Global Development Programs, Gates Foundation

Featured on: April 17, 2015

Dr. Elias has been in this role since 2011. He is responsible for all activities outside of the U.S. that are not focused on new medicine development Dr. Elias oversees Global Development's portfolio in Agriculture Development; Family Planning; Financial Services for the Poor; Maternal, Newborn, & Child Health; Polio; Vaccines Delivery; Water, Sanitation & Hygiene; and Special Initiatives. Previously he served as President/CEO of PATH, an international nonprofit organization dedicated to improving the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. Elias currently serves on various advisory boards, including the Nike Foundation and the Duke Global Health Institute. Dr. Elias holds an MD from Creighton University, having completed postgraduate training in internal medicine at the University of California San Francisco, and an MPH from the University of Washington. medicine) from Creighton/UCSF, MPH from University of Washington.



# Pharmaceutical services firm Resilience debuts, with questions

New company pitches itself as a disruptive engineering services firm in biopharmaceutical manufacturing

by **Rick Mullin**

November 25, 2020 | A version of this story appeared in **Volume 98, Issue 46**

Resilience, a venture-backed biopharmaceutical manufacturing services firm, has made its debut with an announcement of \$800 million in the bank, a roster of highly-accomplished leaders, and an intent to develop “powerful new technologies”



As a first step, Resilience has acquired Therapure Biopharma, a biologics services firm in Mississauga, Ontario, that observers say has been for sale for 3 years. It also purchased an undisclosed protein-based therapy-manufacturing operation in the US, Resilience CEO Rahul Singhvi says. Both deals were closed in October.

In addition, Singhvi says the firm has laboratory space in place in San Diego and a pending deal for lab space in Boston. The company plans to add two more manufacturing sites to its network in 2022. Resilience plans to establish a network of approximately 10 facilities with expertise in biological drug development, says Singhvi, former CEO of the vaccine maker Novavax.

## MOST POPULAR IN BUSINESS

**What is hand sanitizer, and how can it keep your hands germ-free?**

**4 new chemical technologies could make an impact**

**Is ammonia the fuel of the future?**

# Lawmaker Who Led TikTok Ban Bill Joins Private Surveillance Firm: Report

Mike Gallagher pushed the bill to ban TikTok because China can "surveil its users." Now, he's resigning and joining an American surveillance firm

BY CHARISMA MADARANG, ANDREW PEREZ

MARCH 22, 2024



Rep. Mike Gallagher after House passed act th  
WILLIAMS/CQ-ROLL CALL, INC VIA GETTY IMAGES

REPUBLICAN REP. MIKE Gallagher, who led the charge on a bill that could effectively ban TikTok within the country — on the basis that China can “surveil its users” — plans to take up a post with the American surveillance company and defense contractor Palantir, *Forbes* reported.

REPUBLICAN REP. MIKE Gallagher, who led the charge on a bill that could effectively ban TikTok within the country — on the basis that China can “surveil its users” — plans to take up a post with the American surveillance company and defense contractor Palantir. *Forbes* reported.

<https://www.rollingstone.com/politics/politics-news/mike-gallagher-tiktok-ban-palantir-1234993167/>



NEWS 06.14.2021

## Dr. Stephen Hahn, 24th U.S. FDA Commissioner and former Chief Medical Executive at MD Anderson, joins Flagship Pioneering as Chief Medical Officer of its Preemptive Medicine and Health Security Initiative

SHARE [in](#) [X](#)

Stephen Hahn



Hahn in 2019

24th Commissioner of Food and Drugs

Cambridge, Mass, June 14, 2021 – Flagship Pioneering, the bioplatfrom innovation company, announced today that Stephen Hahn, M.D. will help lead its Preemptive Medicine and Health Security initiative as Chief Medical Officer, and join Flagship’s Senior Leadership Team, effective June 16, 2021. Dr. Hahn served as the U.S. Food and Drug Administration Commissioner from 2019–2021. Prior to joining the FDA, he was the Chief Medical Executive, The University of Texas MD Anderson Cancer Center.

During his time as the 24th Commissioner of the U.S. Food and Drug Administration, Dr. Hahn led the 17,000+ person agency that regulates approximately 20 percent of consumer spending in the United States. He oversaw both COVID and non-COVID regulatory affairs, including therapeutics and vaccine development, devices, diagnostics, and clinical trials.



# Stephen Hahn

---

Article [Talk](#)

---

From Wikipedia, the free encyclopedia

*For other people named Stephen Hahn, see [Stephen Hahn \(disambiguation\)](#).*

**Stephen Michael Hahn** (born January 22, 1960) is an American [physician](#) who served as the [commissioner of food and drugs](#) from 2019 to 2021. Before becoming commissioner, he was an oncologist serving as chief medical executive of the [MD Anderson Cancer Center](#). In 2021, he became chief medical officer at [Flagship Pioneering](#), the venture capital firm that launched [Moderna](#).

[https://en.wikipedia.org/wiki/Stephen\\_Hahn](https://en.wikipedia.org/wiki/Stephen_Hahn)



# Receipts

[https://cancerletter.com/covid-19-cancer/20210212\\_4/](https://cancerletter.com/covid-19-cancer/20210212_4/)

<https://cen.acs.org/business/outourcing/Pharmaceutical-services-firm-Resilience-debuts/98/i46>

[https://ec.europa.eu/commission/presscorner/detail/en/IP\\_23\\_3043](https://ec.europa.eu/commission/presscorner/detail/en/IP_23_3043)

[https://commission.europa.eu/strategy-and-policy/coronavirus-response\\_en](https://commission.europa.eu/strategy-and-policy/coronavirus-response_en)

[https://commission.europa.eu/strategy-and-policy/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate\\_en](https://commission.europa.eu/strategy-and-policy/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en)

[https://insmed.com/annual\\_report/2020/Insmed\\_2020\\_AnnualReport.pdf](https://insmed.com/annual_report/2020/Insmed_2020_AnnualReport.pdf)

<https://www.lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=368948>

<https://www.mississauga.com/news/>

<https://live.worldbank.org/experts/christopher-elias>

<https://www.gpmb.org/annual-reports/annual-report-2019>

<https://www.weforum.org/press/2019/10/live-simulation-exercise-to-prepare-public-and-private-leaders-for-pandemic-response>

<https://www.biotalent.ca/organizations/resilience-biotechnologies/>

<https://www.cnn.com/2021/11/12/health/covid-cancer-biontech-ugur-sahin/index.html>

<https://www.fao.org/3/cc1533en/cc1533en.pdf>

<https://www.gpmb.org/about-us>

[https://www.gpmb.org/docs/librariesprovider17/default-document-library/gpmb-manifesto-2023.pdf?sfvrsn=f8ac828b\\_11](https://www.gpmb.org/docs/librariesprovider17/default-document-library/gpmb-manifesto-2023.pdf?sfvrsn=f8ac828b_11)

Global Health Summit 2021: <https://www.youtube.com/live/JWUIMRPgBuQ?feature=share>



[alachu/%20%7C%20Nanotherapeutics%20Breaks%20Ground%20on%20New%20Facility%20in%20Alachu%20-](#)



